IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

DePuy Mitek, Inc.'s Memorandum In Support of Its Motion To Preclude Arthrex, Inc. and Pearsalls Ltd. From "Supplementing" Their Expert Reports and Depositions

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I. Introduction

Plaintiff, DePuy Mitek, Inc. ("Mitek"), requests an order preventing Defendants, Arthrex, Inc. and Pearsalls, Inc., (collectively, "Arthrex")[1] from "supplementing" their technical expert reports.

With only three months to trial, Arthrex has belatedly recognized that it has serious problems with the expert testing and reports it submitted to try to prove that its accused FiberWire sutures do not infringe Mitek's Hunter Patent. As spelled out in the July 14 Amended Supplemental Report of Mitek's expert, Dr. David Brookstein, the methodology Arthrex's experts used to carry out Arthrex's "noninfringement" tests was significantly flawed, and the results were contradictory. Arthrex also has a problem in that the expert who submitted the expert report outlining the "noninfringement" tests, Dr. Gitis, and the expert who is supposed to rely on those tests and offer an opinion of noninfringement, Dr. Mukherjee, both showed at their depositions that neither could explain the significance of Dr. Gitis' test results.

On the heels of receiving Dr. Brookstein's Amended Supplemental Report, Arthrex informed Mitek that Dr. Gitis' data "may have been" affected by a computer virus and that he would be re-doing his tests and issuing a new expert report (Ex. 7). These belated allegations – the 21st Century equivalent to the "dog ate my homework" excuse – are unsupported and incredible. Arthrex offers too little explanation too late, and giving Arthrex a second chance at this late date would be contrary to the rules and would be highly prejudicial to Mitek. The focus now should be on preparing for trial. Arthrex should be precluded from "supplementing" or re-doing expert reports at this late date.

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[1] Arthrex and Pearsalls are jointly represented by the same counsel and have jointly submitted expert reports. Generally, Arthrex and Pearsalls have not distinguished between their defenses. Accordingly, Mitek generally uses "Arthrex" to refer to both Arthrex and Pearsalls in this motion.

II. Background

A. Nature and Stage of the Case

Mitek and Arthrex compete for sales of sports-medicine, medical devices. Mitek is based outside of Boston, and Arthrex is based in Naples, Florida. The other defendant in this action is Pearsalls, who manufactures and imports into the United States products for Arthrex. Pearsalls is a foreign company located in rural England.

This is a patent infringement action involving Mitek's U.S. Patent No. 5,314,446 which claims surgical sutures and suture products (Ex. 1 at 8:62-10:19). Arthrex's sale of its FiberWire sutures and suture products infringes Mitek's 446 Patent; Pearsalls' importation and sales of suture braids constitute contributory infringement.

Fact and expert discovery are closed. Claim construction briefs and dispositive motions are due this week on August 11 (D. I. 27 & June 16, 2006 Minute Order). A jury trial is scheduled to commence on November 13, 2006 (*id.*).

B. Arthrex's Belated Allegation of a Computer Virus

Mitek's 446 Patent claims surgical sutures and other surgical products that have a novel construction of certain dissimilar materials braided together (Ex. 1 at 8:62-9:10). As the 446 Patent explains, the claimed sutures have enhanced properties attributable to the dissimilar materials (*id.* at 2:49-52). Arthrex specifically engineered its FiberWire suture product to be dissimilar materials braided together, with enhanced properties attributable to the dissimilar materials (Ex. 2, Expert Rpt. of Dr. David Brookstein, at ¶¶28-32; Ex. 3, Dr. Brookstein's Rebuttal Rpt., at ¶¶27-36).

Even though the 446 Patent expressly teaches that the sutures of its invention can be coated (Ex. 1 at 6:5-17), Arthrex alleges that a coating on its FiberWire sutures somehow renders the sutures noninfringing. As Mitek understands Arthrex's argument, Arthrex alleges that

FiberWire's surface coating "materially affects" certain alleged "basic and novel characteristics of the inventions" claimed in the 446 Patent. In support of this position, one of Arthrex's technical experts, Dr. Norman Gitis, conducted a series of tests purporting to compare the properties of "coated" suture with "uncoated" suture, and reported those tests in his expert report (Ex. 4, Dr. Gitis' Report). The tests allegedly included tests for certain suture properties, including pliability, knot slippage strength, knot run down, friction, tissue drag, and chatter (*id.*). Another of Arthrex's technical witnesses, Dr. Mukherjee, reviewed and relied on Dr. Gitis' report in giving his opinion that the FiberWire sutures are non-infringing (Ex. 5, Dr. Mukherjee's Responsive Rpt., at 2, referring to Dr. Gitis report as the "reports prepared by the Center for Tribology, Inc."). Dr. Gitis' and Dr. Mukherjee's expert reports were served on March 24, 2006.

Because the 446 Patent is not about coatings, but rather about braiding certain dissimilar fiber-forming materials together, Mitek disagrees with Arthrex's position that Arthrex's sutures are non-infringing because they have a coating (Ex. 3, Dr. Brookstein's Rebuttal Rpt., at ¶¶22-54). Nevertheless, Mitek's expert, Dr. David Brookstein, spent months analyzing Dr. Gitis' tests and analyses and concluded that his work was essentially meaningless and irrelevant (*id.* at ¶¶43-52 & Ex. 6, Dr. Brookstein's Amended Supp. Rpt.). In his July 14 Supplemental Expert Report,[2] Dr. Brookstein opined that Dr. Gitis' methodology was significantly flawed because, *inter alia*, he did not test samples that were really "coated" against "uncoated," his testing methodology

[2] On March 28, 2006, immediately after receiving Dr. Gitis' report, Mitek requested, *inter alia*, the data underlying Dr. Gitis' tests, his test protocols, and discovery of the construction and manufacturing of the samples that he tested (Ex. 10). Despite numerous requests for this information, Arthrex's counsel was not able to produce it before rebuttal expert reports were due on April 13, 2006 (Exs. 11-14). Although Arthrex's counsel had a mid-April trial, it was not able to even produce information in its possession before April 13, 2006 (*id.*). Thus, the parties agreed that Dr. Brookstein could supplement his report after Arthrex provided the requested information (Ex. 15).

was flawed, and Dr. Gitis' test results contradicted some of Arthrex's positions (Ex. 6, Dr. Brookstein's Amended Supp. Rpt.[3], at ¶¶35, 43).

Three months after Dr. Brookstein's Rebuttal Report, a month after Dr. Gitis' deposition and eleven days after Dr. Brookstein's Supplemental Report was served – but a full *four months* after Dr. Gitis had served the report now criticized by Dr. Brookstein – Arthrex informed Mitek that Dr. Gitis' data "may have been" affected by a computer virus and that he would be redoing his tests and issuing a new expert report (Ex. 7) (emphasis added). Mitek immediately requested information regarding the alleged virus and how it affected Dr. Gitis' work (Ex. 8). To date, Mitek has received no response to this letter.

On August 1, the parties discussed the issues, but were unable to resolve them. Mitek advised Arthrex that it would be filing a motion to preclude Arthrex from "supplementing" expert reports. Later that day, Arthrex informed Mitek that Dr. Gitis would be out of the country for the next couple of weeks due to an unexplained, unexpected emergency (Ex. 9).

III. Arthrex Should Not Be Permitted To Redo Expert Reports and Discovery

A. Legal Requirements for "Supplementing" Expert Reports

FED.R.CIV.P. 26(e)(1) provides a "limited exception" for *supplementing* an expert's report. *Minebea Co., Ltd. v. Papst*, 231 F.R.D. 3, 7 (D. D.C. 2005). In relevant part, FED.R.CIV.P. 26(e)(1) provides that a party may "supplement" an expert report "if the party learns that in some material respect the information disclosed is incomplete or incorrect and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing."

[3] On August 24, 2006, Dr. Brookstein submitted an Amended Supplemental Expert Report to correct a typographical error. In all other respects, Dr. Brookstein's Amended Supplemental Report is identical to his Supplemental Expert Report dated July 14, 2006.

Although Arthrex has characterized its intended actions as "supplementing" the Gitis report, it is clear that what it is really intending to do is "redo" the Gitis tests and the report. The Federal Rules do not contain a provision for *redoing* expert reports. *DAG Enters., Inc. v. Exxon Mobil Corp.*, 226 F.R.D. 95, 109-10 (D. D.C. 2005) (holding that supplementation does not permit a party to simply substitute an old report for a new one); 6 JAMES WM. MOORE ET AL., MOORE'S FEDERAL PRACTICE ¶ 26.131[2] (3d ed. 2006) (explaining that "[a] party may not use a supplemental report to disclose information that should have been disclosed in the initial report, thereby circumventing the requirement for a timely and complete report") (Ex. 16).

Nor does Rule 26(e)(1) grant a party the right to supplement reports merely because it believes such reports would be "desirable" or "necessary." *Minebea*, 231 F.R.D. at 7 (*citing Keener v. United States*, 181 F.R.D. 639, 640 (D. Mont. 1998)). Rather, the supplementation permitted by Rule 26(e)(1) is generally limited to the "narrow purpose of correcting inaccuracies or adding information that was not available at the time of the initial report." *Id.*; *DAG Enters.*, 226 F.R.D. at 109-110 (holding that "supplementation under the Rules means correcting inaccuracies, or filling the interstices of an incomplete report," not substituting reports). A factor in denying requests for supplementation is whether the information was known to the party requesting supplementation before expert discovery closed.[4]

[4] *Minebea*, 231 F.R.D. at 7 (citing *Keener*, 181 F.R.D. at 640); *Saint-Gobain Corp. v. Gemtron Corp.*, No. 1:04-cv-387, 2006 U.S. Dist. LEXIS 28263, at *4-5 (W.D. Mich. May 9, 2006) (Ex. 17) (holding that expert could not supplement where party trying to supplement could not show that the new information was unknown to it); *Schweizer v. DEKALB Swine Breeders, Inc.* 954 F. Supp. 1495, 1510 (D. Kan. 1997) (excluding supplemental report of expert containing new opinions when there was no reason the opinions could not have been expressed in the expert's original report).

B. Arthrex Has Not Provided a Legitimate Reason for Redoing Expert Reports and Discovery

Even if what Arthrex plans to do could properly be characterized as merely "supplementing" its expert reports, it has provided no legitimate reason for being permitted to do so. Rule 26 requires Arthrex to show that Dr. Gitis' report was either "inaccurate" or "incomplete" based on the alleged virus. Arthrex has shown neither. Nor has Arthrex shown that the virus information was previously unknown to Dr. Gitis.

1. Arthrex Has Not Shown That Dr. Gitis' Report Was "Inaccurate" or "Incomplete" Due To a Virus

According to Arthrex, the only alleged reason for redoing expert reports is that Dr. Gitis' report "*may* be based upon data that was corrupted" (Ex. 7) (emphasis added). But an unsubstantiated allegation that a virus "may" have occurred is not proof that it did occur. Nor is a bare allegation of data corruption proof of an "inaccuracy" or omission that resulted from the virus. Absent proof of the virus itself and of a material inaccuracy or omission resulting from the virus, there is no justification for supplementation.[5]

Arthrex's virus/corruption allegations are belied by the record evidence. Dr. Gitis' report, on its face, shows no indication of data corruption (Ex. 4). Further, the disk containing

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[5] *Saint-Gobain Corp.*, 2006 U.S. Dist. LEXIS 28263, at *4-5 (holding that expert could not supplement where Rule 26(e)(1) not satisfied) (Ex. 17); *White v. Cinemark USA, Inc.*, No. 2:04-cv-397-GEB-CMK, 2005 U.S. Dist. LEXIS 42134, at *9-10 (E.D. Cal. Aug. 3, 2005) (Ex. 24) (holding that there was no reason to supplement where the proponent of the report declared that the original report was neither inaccurate not incomplete); *Coles v. Perry*, 217 F.R.D. 1, 3 (D. D.C. 2003) (striking late-filed report styled "supplemental opinion," noting that "Fed. R. Civ. P. 26(e) does not grant a license to supplement a previously filed expert report because a party wants to"); *Akeva L.L.C. v. Mizuni Corp.*, 212 F.R.D. 306, 310 (M.D. N.C. 2002) (holding that Rule 26(e)(1) "does not cover failures of omission because the expert did an inadequate or incomplete preparation"); *Stein v. Foamex Int'l, Inc.*, No. 00-2356, 2001 U.S. Dist. LEXIS 12211, at *15 (E.D. Pa. Aug. 15, 2001) (Ex. 18) (holding that a late filed affidavit was not a supplemental expert report because it does not contradict the original report in any material respect); *Keener*, 181 F.R.D. at 640 (second expert report was not a supplemental report because it was not shown that the first report was inaccurate or incomplete in some material respect).

Dr. Gitis' data works just fine. In fact, the computer disk shows, line-by-line, tens of thousands of data points that Dr. Gitis collected during his experiments and does not reflect any corruption.[6] A virus typically corrupts data so that it is not usable; it generally does not change data.

Not only is there nothing on the face of the Gitis Report or the underlying data to indicate corruption, but Dr. Gitis testified that he "checked the results" of his tests (Ex. 19, Dr. Gitis' Dep., at 85:12-18). He further testified that he did not "remember 100 percent, *but I am almost sure that I checked all the calculations in all the tests"* (*id.* at 85:12-18; 197:22-24) (emphasis added). Thus, the record evidence is that there was no data corruption by any virus.

Arthrex should not be permitted to redo its expert reports because, at this point, the virus is nothing more than an unproven allegation that fails to satisfy the requirements of Rule 26(e)(1).

If Arthrex is not denied, outright, the chance to redo its expert reports, it should first be ordered to make an offer of proof explaining specifically how Dr. Gitis' report was "inaccurate" or "incomplete" due to this alleged virus. Arthrex's offer of proof should include:

- proof of what the virus was;
- proof of what machines were affected;
- proof of how the virus affected the machines;
- proof of how the virus affected the data;
- proof of how the virus affected Dr. Gitis' analysis and report;
- proof of when this virus occurred;
- proof of when Dr. Gitis was aware of it; and
- an explanation of why Dr. Gitis and Arthrex delayed in raising the issue.

A bare declaration from Dr. Gitis, who is neither a computer science expert nor a virus expert, should not be accepted as proof. Rather, Arthrex's required proof should include forensic computer experts and virus experts that trace how this virus affected Dr. Gitis' work.

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[6] When printed out, Dr. Gitis' data is about 1.5 to 2 bankers boxes of Excel spread sheets.

It is important that Arthrex should have to first prove a virus before Mitek is forced to investigate the veracity of these virus allegations because evaluating them will be costly to Mitek. Mitek will likely have to hire at least two experts: a forensic computer expert to analyze Dr. Gitis' allegedly infected laboratory equipment, and a computer virus expert to analyze whether and how the unidentified virus actually caused an inaccuracy. This will likely involve expert reports and depositions. This is all very expensive and time consuming and Mitek should not be forced to undergo this effort until Arthrex can establish a *prima facia* case regarding its virus.

If Arthrex presents a *prima facia* case that a virus had some material impact on Dr. Gitis' report, and if Arthrex satisfies the other requirements for supplementation, Mitek should then be afforded an opportunity to investigate the accuracies of these proofs. Only if Arthrex can prove what was affected should Arthrex be permitted to redo its work, and only then to the extent that it can prove that corruption occurred.

2. Arthrex's Request To Supplement Should Be Denied Unless Arthrex Can Show that Dr. Gitis Did Not Know About the Virus and Did Not Delay in Raising It

Not only has Arthrex not shown any inaccuracies due to a virus, it has not shown that Dr. Gitis' report was incomplete based on information that was not available to him when he drafted his report or before expert discovery closed. In fact, it defies credibility that a virus could be so serious, yet Dr. Gitis was not aware of it when he generated his report, or at a minimum, well before Arthrex raised the virus allegation on July 24, 2006.

If Dr. Gitis' lab had a virus and it somehow affected his work, Arthrex should have raised the issue months ago, not at the close of expert discovery. Both Arthrex and Dr. Gitis waited until after Mitek's expert, Dr. Brookstein, spent months analyzing Dr. Gitis tests. They waited until after Arthrex's technical witnesses, Dr. Gitis and Dr. Mukherjee, had been deposed in June

2006. They waited until after Mitek traveled to Pearsalls, located in the rural England countryside, at the end of June to conduct discovery on the samples that Dr. Gitis tested. Having inexplicably delayed until expert discovery was closing – over a month after Mitek completed its discovery of Arthrex's experts – Arthrex is hard-pressed to show that any omission was based on information that was not available to it much earlier. Further, if Arthrex's delay caused proof of this alleged virus to be lost, then it should not be permitted to supplement.

IV. If Permitted To "Supplement," Arthrex Should Not Be Permitted To Supplement Beyond Any Proven Inaccuracies Due To the Virus

A. Rule 26(e)(1) Does Not Permit a Party To Redo Expert Discovery

Mitek is concerned that this virus is nothing more than a trumped-up excuse for redoing expert reports that Arthrex now recognizes are flawed. At great expense, Mitek uncovered numerous deficiencies in Dr. Gitis' testing and expert report. But there is no way that these deficiencies could ever be attributed to a virus, even if the existence of a virus were proven. As explained above, Rule 26(e)(1) is not a provision for redoing expert reports under the guise of an unsubstantiated virus.[7] Thus, if Arthrex is allowed to "supplement" its reports at all, that supplementation should be limited to those parts of Dr. Gitis' testing that Arthrex can prove were actually corrupted by the alleged virus.

B. Arthrex Should Not Be Permitted To Correct Dr. Gitis' Test Flaws Which Have Nothing Whatsoever To Do With Any Virus

Dr. Brookstein, Mitek's expert, has criticized Dr. Gitis' work for testing samples that had too many variables. As a result, no cause and effect relationship can be drawn between FiberWire's coating and the outcome of the tests (Ex. 6, Dr. Brookstein's Supp. Rpt., at ¶¶5-10).

[7] *Sharpe v. United States*, 230 F.R.D. 452, 462 (E.D. Va. 2005) (denying supplementation where party sought to correct remedy experts' faulty opinions); *DAG Enters.*, 226 F.R.D. at 109-110 (holding that supplementation does not permit a party to simply substitute an old report for a new one); *Akeva*, 212 F.R.D. at 310 (holding that Rule 26(e)(1) "does not cover failures of omission because the expert did an inadequate or incomplete preparation").

Selecting samples has nothing whatsoever to do with an alleged computer virus. Dr. Gitis obtained those samples from Arthrex's counsel (Ex. 4 at 2, Section 3; Ex. 19, Gitis Dep. at 94:16-20), and Arthrex's counsel obtained the samples from Pearsalls (Ex. 20, PR08458, PR088460). Selection of materials were human decisions and wholly irrelevant to any alleged virus. Thus, Arthrex should not be permitted to use this virus as an excuse for generating new tests.

Further, Dr. Gitis' testing methodology has problems that cannot be attributed to a computer virus. For example, Dr. Gitis purported to conduct a "pliability" test (Ex. 4 at 2-4, Section 5). But Dr. Gitis' so-called "pliability test" was a tension test, not a pliability test (Ex. 3, Dr. Brookstein's Rebuttal Rpt., at ¶¶45-52; Ex. 6, Dr. Brookstein's Supp. Rpt., at ¶¶11-17). After being cross-examined, even Dr. Mukherjee, Arthrex's other expert, admitted that Dr. Gitis did not measure pliability:

> Q. Did you approve the pliability tests that Dr. Gitis did before he did it?
> A. He's the authority. He decided on it and -- and we just did the -- *we didn't measure pliability, all right?* That is the extent of conversation I had. He decided the procedure and the technique.

(Ex. 21, Dr. Mukherjee's Dep., at 425:2-9) (emphasis added) (objection omitted). Further, Dr. Gitis' assumptions underlying his "pliability" test were flawed and his test was improperly conducted (Ex. 3, Dr. Brookstein's Rebuttal Rpt., at ¶¶45-52; Ex. 6, Dr. Brookstein's Supp. Rpt., at ¶¶11-17). These errors have nothing whatsoever to do with an alleged virus.

Dr. Gitis also incorrectly measured the suture diameter with a mechanical device (Ex. 6, Dr. Brookstein's Supp. Rpt., at ¶¶18-22), which has nothing to do with software. Further, during his tissue drag tests, Dr. Gitis did not control testing parameters that affect the outcome of his

tests (*id.* at ¶44). For example, when asked how he controlled the tension force that affects the measured drag or friction, Dr. Gitis admitted that "[w]e didn't control it" (Ex. 19, Dr. Gitis' Dep., at 273:2-5). For his friction test, Dr. Gitis admitted that he did not measure the clamping force on the suture (*id.* at 249:22-24), which also affects the measured friction values.[8]

None of these errors can be attributable to any virus. Arthrex should not be permitted to fix non-virus-caused errors in any of its expert reports.

C. Arthrex Should Not Be Permitted To Try To Change Dr. Gitis' or Dr. Mukherjee's Deposition Testimony Which Has Nothing To Do With An Alleged Virus

Likewise, Arthrex should not be permitted to change or "muddy up" Dr. Gitis' or Dr. Mukherjee's deposition testimony under the guise of a supplemental expert report. Dr. Gitis' and Dr. Mukherjee's deposition statements are not "inaccuracies" within the meaning of Rule 26(e)(1).

For example, Arthrex has a problem in the fact that it has no expert who can explain the relevance of Dr. Gitis' tests. Dr. Gitis admitted that his role was limited to conducting tests and reporting the test results, and he could not attribute any meaning to the test results:

> Q. Have you been asked to provide opinions, or have you just been asked to perform certain tests and provide the test results?
> A. Not -- I have not been asked to provide any opinions, only to test and to produce test results.
>
> Q. Were you asked to draw any opinions or conclusions about what caused the difference in the results?
> THE WITNESS: I was asked by you today, but I was never asked by Dickstein Shapiro.

[8] Dr. Gitis' testing methodology has other flaws; Mitek has provided only a few examples here.

(Ex. 19, Dr. Gitis Dep., at 12:2-7, 312:6-11 (objection omitted); *see also* 62:7-14, 63:9-13). It was apparently Dr. Mukherjee's role to explain the meaning and relevance of Dr. Gitis' tests, but he admitted that he was not an expert in explaining the meaning of Dr. Gitis' tests and test results:

> Q. Are you an expert in explaining the results of this data that Dr. Gitis did and how it relates to FiberWire's coating?
> A. Not really.

(Ex. 21, Dr. Mukherjee's Dep., at 452:16-19; *see also* Ex. 21 at 423:17-424:1; 431:6-433:17; 442:14-443:10; 444:11-17; 446:22-447:7; 450:2-21; 451:7-16; 451:24-452:4; 454:11-455:6; 456:2-9; 457:11-17 (stating that he could not explain Dr. Gitis' data or tests)). Thus, based on Arthrex's experts' deposition testimonies, neither of its technical experts is qualified to explain the significance of Dr. Gitis' tests.[9]

Further, based on Dr. Gitis' deposition testimony, Arthrex has no witness who can even explain many of Dr. Gitis' tests because Dr. Gitis admitted that he did not know how they were conducted. For example, with respect to his knot-run down test (another type of friction test), he testified that he did not know how the end of the suture was controlled (which is important for measuring friction):

> Q. Okay. What happens to the lower one? What happens to the other end?
> A. I don't remember. We didn't describe here, and I don't remember.
> Q. Well, how is the knot running down? I mean, what's holding the other end? Something's got to hold the other end, right --
> A. Right.
> Q. -- if it's a run-down test.
> A. Right. Sorry, I don't remember.

[9] This is reason enough for not permitting Arthrex to redo Dr. Gitis' work because his new work would be irrelevant; there is no Arthrex expert qualified to discuss its significance.

Q. So you can't exactly tell me how this test was done?
A. I have to think about it. I don't remember.

(Ex. 19, Dr. Gitis Dep., at 236:23-237:11). Similarly, Dr. Gitis had no idea how the suture "chatter" data that he reported were determined:

Q. Sure. One thing you could do, I just don't understand how the computer is doing this. One thing you could do is you could take this high point to the next low point, high point to low point, and you figure out that difference for each time and average them; or you can figure out what the high point was, the average high point and the average low point, and take the difference between those two.
A. Yes.
Q. Or there could be some other way you could do this. I don't know.
A. Yeah, I do not remember. I'm sorry.
Q. You don't know?
A. No.

(Ex. 19, Dr. Gitis Dep., at 268:16-269:5). Thus, lacking a witness who can explain Dr. Gitis' tests, Mitek believes that Arthrex wishes to redo the tests and generate new and different deposition testimony. But it should not be permitted to redo its expert reports and expert depositions under the guise of an unsubstantiated virus.

D. Arthrex Should Not Be Permitted To Simply Redo its Expert Work Because It Would Significantly Prejudice Mitek

Permitting Arthrex to redo expert discovery would significantly prejudice Mitek for several reasons. Mitek expended significant resources analyzing Dr. Gitis' work. For example, Mitek's expert Dr. Brookstein spent a significant amount of time analyzing Dr. Gitis' work, preparing a report regarding it, and being deposed about it. His work was extensive. He analyzed Dr. Gitis' testing methodology for six tests, namely pliability, knot slippage strength, knot run-down, friction, chatter, and tissue drag (Ex. 3, Dr. Brookstein's Rebuttal Rpt., at ¶¶43-

52; Ex. 6, Dr. Brookstein's Amended Supp. Rpt.). He also analyzed Dr. Gitis' data from all of the tests which included millions of data points (Ex. 6, Dr. Brookstein's Amended Supp. Rpt.).

Mitek's counsel also spent a significant amount of time analyzing Dr. Gitis' work and conducting discovery regarding his work, including expert depositions. This discovery included a deposition in rural England at Pearsalls to discover the exact nature of the "coated" and "uncoated" sutures tested by Dr. Gitis. Arthrex and Pearsalls refused to answer interrogatories about how the sutures were made, which could have made the depositions unnecessary (Exs. 22-23).[10]

Mitek would be further prejudiced by allowing Arthrex to redo expert reports because of the current posture of this litigation. The November trial date – which Mitek sorely wants to hold – is only three and a half months away. Mitek needs to focus now on claim construction briefing, dispositive motions, and trial preparation. If Arthrex is allowed to redo the Gitis tests, Mitek must start all over again, having its expert analyze the "new" tests and deposing Dr. Gitis and Dr. Mukherjee, not to mention taking the discovery it would be entitled to take to verify the virus allegations in the first place.

If Arthrex really thought it had proof of a virus which would justify a redo of its expert reports, it should have come forward *immediately* with proof of the virus, proof that data were corrupted by the virus, proof of how the corruption occurred, and proof of when Dr. Gitis uncovered the virus. Instead, Arthrex now says that Dr. Gitis is unavailable for several weeks, so the parties will be that much closer to trial – and already into dispositive motion briefing – before any explanation can be offered by Arthrex.

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[10] Arthrex would only answer the interrogatories if Mitek gave up the deposition (Exs. 22 & 23). But Mitek could not agree to that condition in advance of receiving an interrogatory answer because litigants have been known to not completely and precisely answer interrogatories.

At this stage of the case, and under the circumstances presented, permitting Arthrex to scrap Dr. Gitis' work and start over at Mitek's expense is simply not fair and should not be permitted.

At the very least, if Arthrex is permitted to move forward as it proposes, Mitek should be awarded attorney fees, expert fees, and costs associated with dealing with Arthrex's errors. If Arthrex proves that a virus did indeed exist and did indeed corrupt some of Dr. Gitis' data, *and* that Dr. Gitis and Arthrex did not delay in bringing this information forward, Mitek should be awarded fees and costs for taking new expert discovery. Mitek should not be financially penalized for Arthrex's and Dr. Gitis' carelessness in failing to timely recognize the alleged virus. If Arthrex's allegations of a virus and corruption are not substantiated, Mitek should be awarded fees and costs associated with evaluating Arthrex's virus allegations, including its fees and costs associated with this motion.

V. Conclusion

At this point, Arthrex's virus story is nothing more than an unsubstantiated allegation. Arthrex should not be permitted to redo its expert reports and prejudice Mitek simply because Arthrex and Dr. Gitis think that they could have done a better job.

If Arthrex is permitted to try to prove that a virus corrupted its expert data, it should be required to come forward with an offer of proof of: what the virus was, what machines in Dr. Gitis' lab were affected by the virus, how the virus affected the machines, how the virus affected data in Dr. Gitis' report, when the virus occurred, when Dr. Gitis or his lab learned of the virus, and when Arthrex learned of the virus. If the Court deems the offer of proof sufficient, Mitek should then have the opportunity to investigate the virus allegations, including taking discovery and having its own computer forensic experts evaluate Arthrex's allegations.

If, ultimately, Arthrex is permitted to supplement any portion of Dr. Gitis' and Dr. Mukherjee's reports, that supplementation should be limited to parts of the report that were directly affected by the alleged virus contamination.

Finally, Mitek respectfully requests an award of fees and costs, as appropriate, for having to address these issues.

Date: August 9, 2006

/s/ Erich M. Falke

Dianne B. Elderkin
Lynn A. Malinoski
Michael J. Bonella
Erich M. Falke
Woodcock Washburn LLP
One Liberty Place 46th Floor
Philadelphia, PA. 19103
215-568-3100

Daniel J. Gleason (BBO #194900)
Michelle Chassereau Jackson (BBO #654825)
Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA. 02210-2604

CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that true and correct copies of:

DePuy Mitek, Inc.'s Motion to Preclude Arthrex, Inc. and Pearsalls Ltd. From "Supplementing" Their Expert Reports and Depositions; and

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were served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

Charles W. Saber
Dickstein Shapiro
1825 Eye Street, NW
Washington, DC 2006
saberc@dicksteinshapiro.com

Raymond P. Ausrotas
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109
rausrotas@toddweld.com

Dated: August 9, 2006

/s/ Erich M. Falke
Erich M. Falke

US005314446A

United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] **STERILIZED HETEROGENEOUS BRAIDS**

[75] Inventors: **Alastair W. Hunter**, Bridgewater; **Arthur Taylor, Jr.**, Plainfield, both of N.J.; **Mark Steckel**, Maineville, Ohio

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **838,511**

[22] Filed: **Feb. 19, 1992**

[51] **Int. Cl.**[5] **D04C 1/00**

[52] **U.S. Cl.** **606/231**; 606/228; 87/7; 87/9; 428/370

[58] **Field of Search** 606/228, 230, 231; 87/7, 8, 9; 428/225

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,187,752	6/1965	Glick	128/335.5
3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136
4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
5,116,360	5/1992	Pinchuk et al.	623/1
5,147,400	9/1992	Kaplan et al.	623/13

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2949920	3/1981	Fed. Rep. of Germany	A61F 1/00
WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom .	
2218312A	11/1989	United Kingdom	A01K 91/00

Primary Examiner—George F. Lesmes
Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

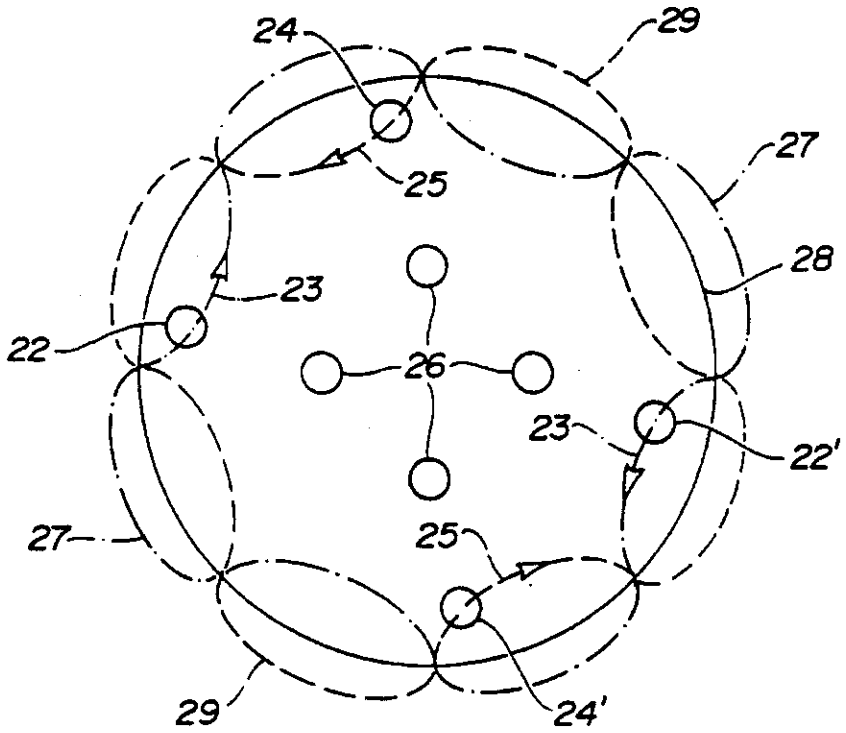
[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1



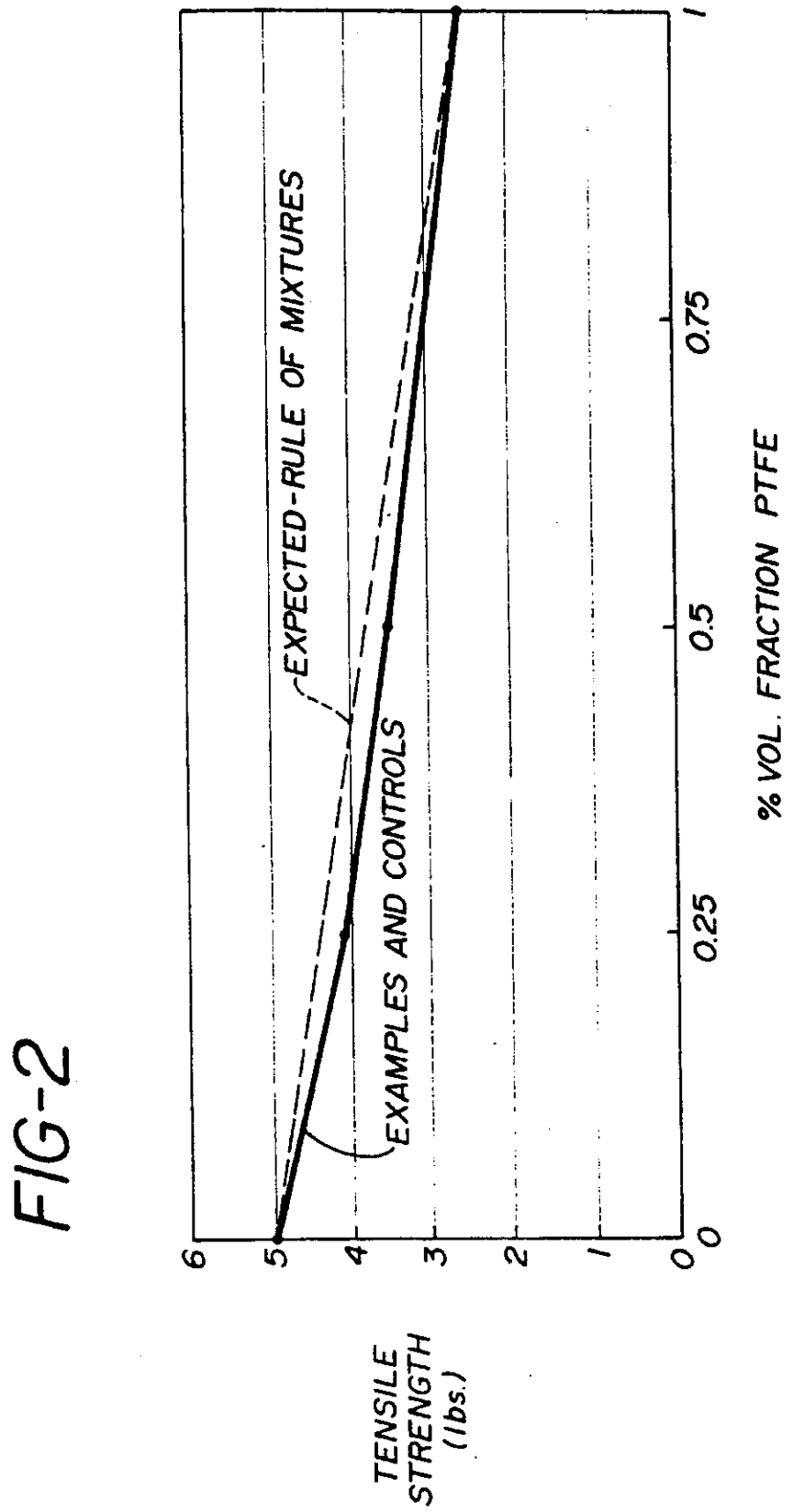
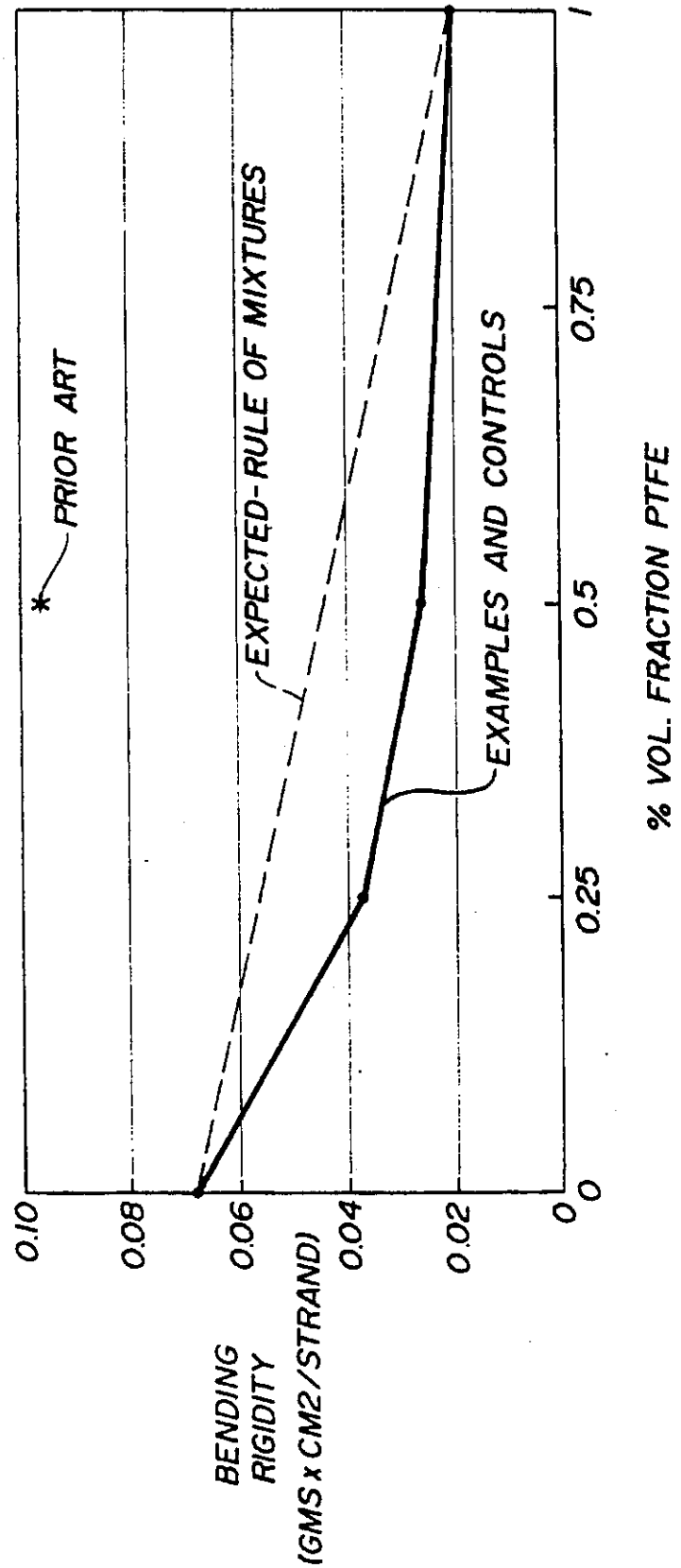

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-2

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
0.10
0.08
0.06
0.04
0.02
0
0.25
0.5
0.75
1
BENDING RIGIDITY (GMS x CM2/STRAND)
% VOL. FRACTION PTFE

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm^2)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogeneous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)(P_a)+(Vf_b)(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

Expert Report of Dr. David Brookstein

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and

conducted research in the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems.

B. Work Experience

5. From 1980 to 1994, I worked at Albany International Research Co. At Albany International Research, I was an Associate Director from 1992 to 1994. From 1983 to 1992, I was an Assistant Director. From 1980 to 1982, I was a Senior Research Associate. While at Albany International Research Co., I directed all activities of the professional engineering group and was responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. My accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous performs for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures.

C. Publications

6. My publications include, among other things:

"Joining Methods of Advanced Braided Composites," Composite Structures, 6, p. 87-95, 1986.

"Structural Applications of Advanced Braided Composites," Proceedings of the SPE Advanced Polymers Composites Division, November 1988.

"Processing Advanced Braided Composite Structures," Proceedings of the WAM of ASME, Materials Division, November 1988.

"Interlocked Fiber Architecture: Braided and Woven," Proceedings of the 35th SAMPE Meeting, April, 1990.

"Evolution of Fabric Preforms for Composites," Journal of Applied Polymer Science: Applied Polymer Symposium, 47, p. 487-500, 1991.

"A Comparison of Multilayer Interlocked Braided Composites with Other 3-D Braided Composites," 3rd International Techtextil Symposium, 14-16, May 1991, Frankfurt.

"On the Mechanical Behavior of 3-D Multilayer Interlock Braided Composites," with Preller, T., and Brandt, J., DASA-Deutsche Aerospace, Proceedings of NASA Fiber-Tex '92.

"The Solid Section Multilayer Interlock Braiding System," 4th International Techtextil Symposium, 4 June 1992, Frankfurt.

"On the Mechanical Properties of Three-Dimensional Multilayer Interlock Braided Composites, TECHTEXTIL Symposium, 1993, Frankfurt.

"3-D Braided Composites-Design and Applications," Sixth European Conference on Composite Materials, 20-24 September 1993, Bordeaux.

"Concurrent Engineering of 3-D Textile Preforms for Composites," International Journal of Materials and Product Technology, Vol. 9, Nos. 1/2/3, 1994.

"Physical Properties of Twisted Structures" with Ning Pan, Fiber Society Symposium, Asheville, NC, 1998.

D. Patents

7. I am an inventor on the following U.S. Patents:

U.S. Patent 4,290,170 - "Device for Aligning and Attenuating Fiber Mats," A device for producing aligned carbon fiber webs for use in composites.

U.S. Patent 4,497,866 - "Sucker Rod," An elliptical cross-section braided composite rod for pumping oil.

U.S. Patent 4,602,892 - "Sucker Rod," A braided composite rod and coupling for pumping oil.

U.S. Patent 4,841,613 - "Pressure Developer or Press Roll Containing Composite Material," A composite press roll with variation of radial stiffness.

U.S. Patent 4,909,127 - "Braiders," A braider with non-circular braider tracks and a unique package carrier for use with braider.

U.S. Patent 5,004,474 - "Prosthetic Anterior Cruciate Ligament Design," An artificial ligament device having a tubular woven ligament and being adapted for joining the ends of two bones.

U.S. Patent 5,357,839 - "Solid Braid Structure" A 3-D system for producing braids.

U.S. Patent 5,358,758 - "Structural Member" A fiber reinforced structural member produced from a complex woven fabric.

U.S. Patent 5,411,463 - "Composite Roll and Method of Making" A fiber reinforced roll for papermaking.

U.S. Patent 5,501,133 - "Apparatus for Making a Braid Structure" A novel manufacturing system for producing 3-D multilayer interlock braided textile and fiber reinforced composite structures.

U.S. Patent 5,697,969 - "Vascular Prosthesis and Method for Implanting" A fibrous synthetic vascular graft with a combination of resorbable and non-resorbable layers.

E. Education

8. I have a Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.

9. I have a Master of Science in Textile Technology from M.I.T., 1973.

10. I also hold a Bachelor of Textile Engineering, from Georgia Tech, 1971.

11. I also attended the Harvard Business School Summer Program on Research Management in 1990 and the Harvard Graduate School of Education MLE Summer Program, 1998.

12. When I was a researcher at Albany International Research Co., in the late 1980's, I led a program that involved the development of braided sutures for a commercial client. While at Albany, I researched, developed, tested and evaluated numerous braided and woven biomedical implants, including woven ACL prosthesis, braided artificial arteries, and textile-based, resorbable bone plates and screws. Furthermore, I have taught textile engineers at the undergraduate and graduate level at Philadelphia University materials that involve the design, construction, braiding, manufacturing, and processing of textile structures that includes braids. Specifically, among other things, I have taught courses in Fiber Science which include fiber and yarn tensile, bending, and compression properties. Additionally, I was awarded the TechTextil Innovation Prize (Germany) in 1993 for my work in braiding.

13. A copy of my CV is attached under Tab A. A list of my publications and patents are set forth in my CV . Over the past four years, I have been deposed or testified as an Expert Witness in five cases. A complete list of cases in which I have provided testimony within the past four years is attached under Tab B. A list of the documents that I used in forming my opinions is set forth in Tab C.

14. I have been engaged by counsel of DePuy Mitek as a consultant in this litigation at a consulting rate of $300/hour.

II. Summary of Opinions

15. It is my opinion that sales of Arthrex's FiberWire™ and TigerWire™ suture products (in all sizes and regardless of whether it is attached to needle, or any other component)

literally infringe claims 1, 2, 8, 9, and 12 of U.S. Patent No. 5,314,446 (the '446 Patent) (Tab D). I understand that Arthrex sells FiberWire™ in the United States as free strands, attached to needles of various sizes, and attached to anchors used in various surgical applications (*e.g.*, rotator cuff repair, shoulder instability procedures). I further understand that Arthrex sells TigerWire™ in the United States attached to needles and anchors. I use the term "FiberWire™ suture products" to refer to all FiberWire™ products regardless of whether they are free strands, attached to needles, or attached to anchors. I use the term "TigerWire™ suture products" to refer to all TigerWire™ products regardless of whether they are sold attached to anchors or needles.

16. It is my opinion that sale of Arthrex's FiberWire™ and TigerWire™ suture products (in all suture sizes) directly infringes claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents.

17. I understand that Pearsalls imports into, and sells in, the United States unsterile, untipped FiberWire™ and TigerWire™. It is my opinion that such unsterile, untipped products are a component of the invention claimed in the '446 patent and constitute a material part of the invention claimed in claims 1, 2, 8, 9, and 12 of the '446 patent.

18. It is my opinion that the FiberWire™ and TigerWire™ sutures imported and sold by Pearsalls are especially adapted for use in infringement of claims 1, 2, 8, 9, and 12 of the 446 Patent, and are not a staple article or commodity of commerce suitable for substantial noninfringing use.

19. It is my opinion that some of the benefits of FiberWire™ and TigerWire™ sutures are due to the invention, claimed in claims 1, 2, 8, 9, and 12 of the 446 Patent.

III. Materials Considered in Forming My Opinions

20. I understand that Arthrex has admitted that Pearsalls manufactures the Arthrex FiberWire™ and TigerWire™ suture. (Arthrex's Response to Mitek Interrogatory #2). I

attended the Pearsalls plant inspection and deposition in Taunton, Somerset, England on January 11, 2006. Mr. Brian Hallet testified on behalf of Pearsalls. While attending the Pearsalls plant inspection, I personally observed the manufacturing processes used to make the braid that comprises the FiberWire™ and TigerWire™ sutures. I may testify about the manufacturing process that I observed on January 11, 2006 at Pearsalls and the explanation of it as set forth by Pearsalls at depositions and in documents. I may use videotape deposition testimony or exhibits made from the videotape to aid me in testifying.

21. The manufacturing process to make the FiberWire™ and TigerWire™ suture braids that I observed includes the following steps: twisting core and sheath yarns, steam setting core and sheath, winding braider bobbins, braiding, winding to skein, scouring, dyeing, stretching, coating, and thermal treating, and subsequent inspection. I also observed Pearsall's testing laboratory. I may testify about each of these processes and the Pearsalls' equipment used in the manufacturing and testing processes. In addition to observing the manufacturing processes, I have also reviewed documents that describe them (DMI Exs. 279, 281, 287-312). I may rely on these documents in testifying about FiberWire™ and TigerWire™.

22. I have reviewed technical documents concerning FiberWire™'s and TigerWire™'s construction and manufacturing. I have also reviewed deposition transcripts of technical witnesses concerning FiberWire™ and TigerWire™, including the depositions of, among others, Arthrex Engineer, Peter Dreyfuss, Arthrex's Vice President of Operations Kevin Grieff, and Pearsalls' Brian Hallet. A list of the documents that I used in forming my opinions is set forth in Tab C.

23. I have examined samples of FiberWire™ and samples of FiberWire™ taken at various stages of the manufacturing processes (DMI Exs. 282, 283, 284, 285, 342 and Bates nos. ARM 25451-52, and ARM 25590).

IV. Legal Framework of My Opinions

I have been told by counsel to apply the following principles of United States Patent law in my analysis.

A. Direct Infringement

24. I understand that the statutory basis for a determination of direct patent infringement is set forth in 35 U.S.C. §271(a) which states:

> Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any Patented invention, within the United States or imports into the United States any Patented invention during the term of the Patent therefore, infringes the Patent.

25. I understand that an analysis of direct infringement requires two steps. First, the Court determines the meaning of the claims. Then, the properly construed claims are applied to a product to determine whether it infringes the Patent. I understand there are two types of direct infringement -- literal infringement and infringement under the doctrine of equivalents.

26. Infringement is "literal" when each claim limitation is literally present in a device. I understand that even if a device does not literally have each claim limitation, there is still infringement if the device has an equivalent of the claimed limitation that is not literally present. I understand that one method for determining whether a structure is equivalent to a claim limitation is the insubstantial differences test. Under this test, if the differences between the structure and the claim element are insubstantial, then they are equivalent. One method for determining whether the differences are insubstantial is whether the structure in the accused

device "performs substantially the same function in substantially the same way to obtain the same result" ("function/way/result test") as the claimed element.

V. Direct Infringement

A. Claim Construction

27. As mentioned above, I understand that the first step in an infringement analysis is to construe the claims. I understand that the Court will determine the meaning of the claim terms in the '446 Patent. Until the Court determines the meaning of the claims, I have been asked to assume the meaning of the following claim terms.

"PE" – means all types of polyethylene (PE) including ultra high molecular weight polyethylene.

"consisting essentially of" – means the claimed suture with all of its limitations and any other unlisted materials that do not materially affect the basic and novel characteristics of the claimed suture.

I have been told that the Court will determine the basic and novel characteristics of the claimed invention. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

"direct intertwining contact" –means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

"volume fraction of the first set of yarns in the braided sheath and core" means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

I reserve the right to modify my opinion should the Court determine the meaning of the claims are different than the above constructions provided by counsel.

B. Literal Infringement

28. I have been asked to provide my expert opinion regarding whether Arthrex's FiberWire™ and TigerWire™ suture products infringe claims 1, 2, 8, 9, and 12 of the '446 Patent. It is my opinion that Arthrex's FiberWire™ and TigerWire™ suture products infringe claims 1, 2, 8, 9, and 12 of the '446 Patent. It is my understanding that Arthrex has offered for sale or sold each of its FiberWire™ and TigerWire™ suture products within the United States. Therefore, there is literal infringement because, as described below, each of Arthrex's FiberWire™ and TigerWire™ suture products literally has all of the limitations of claims 1, 2, 8, 9, and 12. In determining literal infringement, I first consider the construction of FiberWire™ and TigerWire™. Then, I compare the claims, with the definitions as provided above, to the FiberWire™ and TigerWire™ suture products.

1. Arthrex's FiberWire™ and TigerWire™ Suture Products

29. I understand that all Arthrex's FiberWire™ suture, except size 4-0, is made of a core of polyethylene yarns (of the ultra high molecular weight type) and a braided sheath of polyethylene yarns (of the ultra high molecular weight type) and PET yarns (Dreyfuss 9/16/05 Dep. at 43, 55-57). The braided sheath is made by having one set of carriers, which have polyethylene, traversing the braider bed in a serpentine and clockwise fashion and the other set of carriers, which have PET, traversing the braider bed in a serpentine counter-clockwise fashion. I understand that Arthrex sells only sizes 5, 2, 0, 2-0, 3-0, and 4-0 FiberWire™ (Dreyfuss 9/16/05 Dep. at 31). I understand that the description of FiberWire™ is generally described in Arthrex's 510K for FiberWire™ (DMI Ex. 78 at ARM 001899).

30. I also understand that no. 2 Arthrex TigerWire™ is basically identical to no. 2 FiberWire™ with one exception. TigerWire™ has one black nylon yarn that replaces one of the PET yarns in no. 2 FiberWire™. No. 2 TigerWire™ has 8 yarns of PE, 7 yarns of PET, and 1 yarn of nylon braided together. (DMI Ex. 318) I also understand that Arthrex sells TigerWire™ in only size no. 2 (Dreyfuss 9/16/05 Dep. at 106). I understand that Arthrex also sells a TigerTail™[1] product that "is a version of FiberWire™ suture with a black strand that creates spiral marking along one-half length of the suture" (DMI Ex. 318).

31. I understand that FiberWire™ and TigerWire™ have been made with "Spectra" and "Dyneema" ultra high molecular weight polyethylene yarns in manufacturing the FiberWire™ suture (Dreyfuss Dep. p. 44-45, Grieff Dep. 9/15/05 p. 22-23, and 51). Spectra and Dyneema are trade names for certain companies' ultra high molecular weight polyethylene.

32. Arthrex's FiberWire™ and TigerWire™ suture is coated with NuSil Med-2174 manufactured by NuSil technology. (Dreyfuss 9/16/05 Dep. at 42). NuSil MED-2174 is generally described at DMI Ex. 78 at ARM 1933-36. I also understand that Arthrex sells a FiberStick™[2] product. I understand FiberStick™ to be a 50 inch piece of FiberWire™ that has 12 inches of its length stiffened with Loc-Tite (DMI Ex. 3 and Dreyfuss 9/16/05 Dep. at p. 122).

[1] Because TigerTail™ includes FiberWire™, TigerTail™ infringes the '446 patent for the same reasons that FiberWire™ infringes.

[2] Because FiberStick™ includes a portion of FiberWire™, FiberStick™ infringes the '446 patent for the same reasons that FiberWire™ does.

2. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Claim 1

33. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products[3] literally infringe claim 1 of the '446 because they literally have all of the limitations of claim 1 as set forth below.

Claim 1 of the '446 Patent	**FiberWire™ and TigerWire™ Suture Products**
A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and	The sterilized FiberWire™ and TigerWire™ suture is a braid of polyethylene (PE) and polyester (PET).[4] The PE and PET yarns are both continuous and discrete. The PE and PET are mechanically intertwined so that at least one PE yarn and one PET yarn are braided in direct intertwining contact. (DMI Ex. 318)
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The FiberWire™ and TigerWire™ suture is made from PE yarns that are made of a plurality of PE filaments. (Dreyfuss 9/16/05 Dep. at p. 50:21-51:1)

[3] I understand that Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3). To the extent that I have not recited a specific Arthrex product by name or code, if any unrecited product includes any portion of a FiberWire™ or TigerWire™ suture, it would infringe claims 1, 2, 8, 9, and 12 of the '446 patent for the same reasons stated herein.

[4] Q. And what incoming yarns are received by Pearsalls when Pearsalls manufactures and braids the bulk sutures made for Arthrex's FiberWire™ sutures?
A. Incoming yarns would be ultra high molecular weight polyethylene and PET. (Dreyfuss 9/16/05 Dep. at p. 43:15-19)

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon, and aramid; and	The FiberWire™ and TigerWire™ suture is made from PET yarns that are made of a plurality of PET filaments. (Dreyfuss 9/16/05 Dep. at p. 64:14-17)
c) optionally a core.	Arthrex's FiberWire™ sutures have a core except for 4-0 FiberWire™. (DMI Ex. 318)

34. I understand that Arthrex has contended that it does not infringe claim 1 of the '446 Patent for several reasons. To the extent that I understand these positions, I will address them here. I reserve the right to amend or supplement my opinions based on Arthrex's full explanation of its positions.

35. I understand that Arthrex may contend that its FiberWire™ and TigerWire™ products do not infringe claim 1 because they have a coating of NuSil MED-2174. I further understand that the basis of Arthrex's argument is that the coating materially affects the basic and novel characteristics of the claimed invention. As I understand the argument, I disagree with it.

36. As explained above, I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The addition of a coating on FiberWire™ and TigerWire™ does not have any material affect on these basic and novel characteristics. Regardless of the coating, FiberWire™ and TigerWire™ both still have a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The coating

is non-bioabsorbable and does not materially affect bioabsorbability of the yarns, does not materially affect at least one yarn from the first set being in direct intertwining contact with a yarn from the second set, and the coating does not materially affect each yarn from contributing to the overall properties of the heterogeneous braid. Furthermore, Arthrex documents describe the coating as a lubricant (DMI Ex. 78 at ARM1976).

37. The '446 Patent specifically contemplates, in the "Detailed Description of the Invention," that the braided sutures of the invention can be coated (Tab D at 6:5-21). The '446 Patent describes the invention as including applying polymer coatings by making a solution of the polymer and a solvent, immersing the suture in the coating and solvent, and drying the suture (Tab D at 6:9-11). Thus, the '446 Patent's description of the invention as contemplating coatings supports my opinion that FiberWire™'s and TigerWire™'s coatings do not materially affect the novel and basic characteristics of the invention because the inventors specifically contemplated coated sutures. Notably, FiberWire™ and TigerWire™ are coated just as the '446 Patent describes; they are immersed in a solution of NuSil MED-2174 and a solvent and dried.[5]

38. Further, I have taken Scanning Electron Micrographs at the Materials Evaluation laboratory at the Philadelphia University Research Center of DMI exhibit 284 (uncoated), DMI exhibit 342 (coated once), and DMI exhibit 285 (coated twice) FiberWire™ suture braids. My Scanning Electron Micrographs are attached at Tabs E (DMI Ex. 284), F (DMI Ex. 342), G (DMI Ex. 285).

[5] My opinion is further supported because the '446 Patent claims a "suture." I understand that most sutures are coated. Thus, the Patent claims clearly contemplate sutures having coatings, otherwise they would not cover many, if any, sutures.

39. It is my expert opinion and observation from the above Micrographs that the coating on the FiberWire™ suture does not substantially permeate the braided structure and does not reside between the braid yarns.

40. It is my expert opinion and observation that the coating only appears on the surface of the braid.

41. I understand that Arthrex may argue that its FiberWire™ and TigerWire™ suture products do not literally infringe claim 1 because generally at least one end of its FiberWire™ and TigerWire™ suture products are "tipped." I also understand that Arthrex may argue that FiberStick™ does not infringe because about 12 of the 50 inches of its FiberStick™ product is stiffened. With respect to FiberWire™ & TigerWire™, tipping means stiffening the end of the suture with Loc-Tite. (Dreyfuss 9/16/05 Dep at p. 122). To the extent I understand Arthrex's position, I disagree with it.

42. In my opinion, the stiffening and tipping is irrelevant because the remainder of the FiberWire™, TigerWire™, and FiberStick™ suture products are not tipped or stiffened. Thus, at least a significant length of the FiberWire™, TigerWire™ and FiberStick™ suture products infringe. Therefore, regardless of the tipping and stiffening, FiberWire™, TigerWire™, and FiberStick™ infringe for the reasons set forth above.

43. Moreover, it is generally known that multifilament sutures have tipped ends so that they do not fray. Because the claims of the '446 patent are directed to a multifilament suture, it would not make sense for a multifilament suture claim to eliminate almost all multifilament sutures because of such a basic characteristic, *i.e.* tipped ends.

44. As explained above, Arthrex's TigerWire™ is substantially identical to Arthrex's FiberWire™ except that one carrier of PET yarn is replaced with a black nylon strand.

Otherwise, Arthrex's FiberWire™ braid is no different than Arthrex's TigerWire™ braid.[6] I understand that Arthrex contends that its TigerWire™ suture products do not infringe because they have one black nylon strand. To the extent that I understand Arthrex's argument, I disagree.

45. It is my opinion that the nylon marking strand in Arthrex's TigerWire™ suture is non-bioabsorbable and therefore does not materially affect the basic and novel characteristics of the invention in the '446 Patent. For one thing, nylon is expressly mentioned in claim 1 as one of the fiber-forming materials from which the second set yarn can be made. Thus, the inventors contemplated it as being part of their invention, not as changing the basic and novel characteristics of their invention. Further, the inclusion of nylon yarn instead of one yarn of PET (I understand that nylon makes up only 3.4% of TigerWire™ suture, DMI Ex. 318) does not materially affect the basic and novel characteristics of the invention because the braid is still a heterogeneous braid of non-bioabsorbable yarns of the type claimed, at least one yarn of PE is in direct intertwining contact with a PET yarn, and the nylon does not materially affect the yarns from contributing to the properties of the overall braided suture.

46. My opinion is supported by Mr. Dreyfuss' testimony. Mr. Dreyfuss testified on behalf of Arthrex that that the nylon in Arthrex's TigerWire™ suture products is for visual identification and has "minute differences in its feel and strength characteristics" (Dreyfuss 9/16/05 Dep. at p. 75:7-14). Since visual identification is not a basic and novel characteristic, the inclusion of a nylon marker band has no material effect on the basic and novel characteristics of the invention.

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[6] Q. Sure. Sure. Is the braid in any Arthrex TigerWire™ different than the braid used in Arthrex's No. 2 FiberWire™?
A. The braid, no. (Dreyfuss 9/16/05 Dep. at p. 31, line 24 – p. 32, line 2)

3. Arthrex's FiberWire™ and TigerWire™ Needle Products Literally Infringe Claim 2

47. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ needle products[7] literally have all of the limitations of claim 2.

Claim 2	Arthrex's FiberWire™ and TigerWire™ needle products
The surgical suture of claim 1 wherein the suture is attached to a needle.	Each FiberWire™ & TigerWire™ suture needle product has a FiberWire™ suture attached to a needle (DMI Ex. 3).

4. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Claim 8

48. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products[8] literally infringe claim 8 of the '446 for the following reasons:

Literal FiberWire™ Structure	Claim 8
The surgical suture of claim 1 wherein the second set of yarns is PET.	Each FiberWire™ and TigerWire™ suture product has PET as a second set of yarns.

[7] Arthrex's FiberWire™ and TigerWire™ needle products includes all Arthrex's products that are sold with a needle attached to a FiberWire™ or TigerWire™ suture including at least the following Arthrex catalog product codes AR-7200, AR-7202, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7211, AR-7219, AR-7220, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1324BNF, AR-1920BNP, AR-1934BNF, AR-1920BN, AR-1920BNF, AR-1925BNF, AR-1925BNP, AR-1927BNF, AR-1928SNF, and AR-1928SNF-2 (DMI Ex. 3).

[8] I understand that Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3).

	(DMI Ex. 318).

5. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Claim 9

49. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products[9] literally infringe claim 9 of the '446. I have used the following definition of "volume fraction of the first set of yarns in the braided sheath and core" which means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture. For the following reasons, FiberWire™ and TigerWire™ literally infringe claim 9 of the '446 patent for the following reasons:

Claim 9	**Arthrex's FiberWire™ and TigerWire™ Products**
The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to 80 percent.	Every Arthrex's FiberWire™ and TigerWire™ construction has a ratio of the cross-sectional area of UHMWPE in the sheath and core to the total cross sectional area of all the yarns in the surgical suture that ranges from 20 to 80 percent. (DMI Ex. 318).

[9] Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3).

6. Arthrex's FiberWire™ and TigerWire™ Needle Products Literally Infringe Claim 12

50. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ needle products[10] literally have all of the limitations of claim 12.

Claim 12	Arthrex's FiberWire™ and TigerWire™ Needle Products
The surgical suture of claim 8 wherein the suture is attached to a needle.	Arthrex's FiberWire™ and TigerWire™ needle products have either a FiberWire™ or TigerWire™ suture attached to a needle. (DMI Ex. 3).

C. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Under the Doctrines of Equivalents

51. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products also infringe claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents because the differences, if any, between the claims, as I understand they may be construed by Arthrex, and Arthrex's FiberWire™ and TigerWire™ suture products are insubstantial.

52. I understand that Arthrex contends that there is no literal infringement because the claim limitation with respect to the "first-fiber-forming material" is not present because, although FiberWire™ has "PE" or polyethylene, it has one type of "PE," ultra high molecular weight polyethylene (UHMWPE). If it is determined that "PE" as claimed does not mean

[10] Arthrex's FiberWire™ and TigerWire™ needle products includes all Arthrex's products that are sold with a needle attached to a FiberWire™ or TigerWire™ suture including at least the following Arthrex catalog product codes AR-7200, AR-7202, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7211, AR-7219, AR-7220, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1324BNF, AR-1920BNP, AR-1934BNF, AR-1920BN, AR-1920BNF, AR-1925BNF, AR-1925BNP, AR-1927BNF, AR-1928SNF, and AR-1928SNF-2 (DMI Ex. 3).

polyethylene (*i.e.*, including UHMWPE), then it is my opinion that there is infringement under the doctrine of equivalents because any differences are insubstantial.

53. I have used the "function/way/result" test to determine infringement of claims 1, 2, 8, 9, and 12 under the doctrine of equivalents. In particular, I have determined the function/way/result of the claim element that Arthrex contends is not literally satisfied and compared that to the function/way/result of UHMWPE in FiberWire™ and TigerWire™.

54. In my opinion, the "function" of the first fiber-forming material is the same as the function of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**Function of Limitation Under the Doctrine of Equivalents**	**Function of UHMWPE in FiberWire™ and TigerWire™ Suture Products**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The function of the first set of yarns is to contribute a property that is different than a yarn from the second set.	UHMWPE contributes different lubricity and strength properties to the heterogeneous braid than PET.

55. My opinion regarding the "function" of the first fiber-forming material is supported by the '446 Patent. The '446 Patent explains that the first fiber forming material is "dissimilar" to the second fiber and the braid of dissimilar yarns provides "outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Tab D at 2:50-52; 3:43-48). Further, the '446 Patent explains that it is possible to "tailor the physical" properties by "varying the type and proportion of each of the dissimilar fiber forming materials used" (Tab D at 2:58-61). Further, the patent notes that the different fiber components make different relative contributions to one or more properties of the heterogeneous braid (Tab D at 8:19-21).

56. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHWMPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

57. In my opinion, the "way" of the first fiber-forming material is the same as the "way" of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**"Way" of Limitation Under the Doctrine of Equivalents**	**Way UHMWPE performs its Function in FiberWire™ and TigerWire™**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The "way" is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set.	At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Dreyfuss 9/16/05 Dep. at p. 99-107).

58. My opinion regarding the "way" of the "first fiber-forming" element is supported by the '446 Patent. The '446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact For example, the '446 Patent states in the "Summary of the Invention" section that the "the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction" and that the at least one yarn from the first set is in "direct

intertwining contact" with a yarn from the second set (Tab D at 2:40-44; *see also* 3:21-28; 3:40-45). The '446 Patent further explains that the heterogeneous braid properties are due to the "mechanical interlocking or weaving of the individual yarns" (Tab D at 2:56-58; 3:43-48). Also, during the prosecution history, the applicants explained that the beneficial properties are due to the braiding of direct "intertwining" contact of dissimilar yarns (December 2, 1992 Office Action at 2, emphasis original).

59. Further, the '446 Patent describes certain preferred embodiments in which the first fiber-forming materials act as lubricating yarns and the second fiber-forming materials provide strength (Tab D at 4:9-59). The '446 Patent also describes other specific preferred embodiments that have PTFE braided in direct intertwining contact with PET to obtain the benefits of each yarn (Tab D at 7:1-8:61). These are all preferred embodiments where the at least one first-fiber forming material is braided in direct intertwining contact with at least one different, second fiber-forming material so that each yarn contributes to the heterogeneous braid. Because these are preferred embodiments, they are an example of the broader disclosed concept of braiding the first and second fiber forming materials so that they can individually contribute to the overall properties of the heterogeneous braid. Notably, the invention is described more broadly than just these "preferred embodiments," and, therefore, it is my opinion that neither the function, way, or result is limited to the specific properties of the first-forming material in any of the preferred embodiments.

60. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products have the same "way" as the claimed first-fiber forming materials. My opinion is based on a visual inspection and observation of FiberWire™ and its manufacturing processes. In my opinion, at least one UHMWPE yarn in Arthrex's FiberWire™ and TigerWire™ products is

braided in direct intertwining contact with at least one PET yarn. My opinion is supported by Arthrex's and Pearsalls' testimony and documents. For example, Mr. Dreyfuss testified that the adjacent yarns in the FiberWire™ and TigerWire™ sheath are in direct intertwining contact with each other (Dreyfuss 9/16/05 Dep. at p. 99-107).

61. In my opinion, the "result" of the first forming material is the same as the result of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**"Result" of Limitation Under the Doctrine of Equivalents**	**Result of UHMWPE in FiberWire™**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The result of the first set of yarns is to contribute to the heterogeneous suture braid a property different from the yarn in the second set, so that when they are braided the yarns contribute to the properties of the overall heterogeneous braid.	The result of the PE yarns is to provide a different property than the PET, so that when they are braided the PE yarns contribute properties to the overall heterogeneous braid.

62. My opinion regarding the "result" of the first-forming material is supported by the '446 Patent. For example, the '446 Patent explains that the "heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials" (Tab D at 2:49-52). Further, the '446 Patent states that the "types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties." (Tab D at 1:51-56).

63. My opinion is that FiberWire™ and TigerWire™ suture products have the same claimed result. UHMWPE has and contributes properties that are different from those provided by PET. For example, Arthrex has admitted that the UHMWPE is added to FiberWire™ to increase strength. (Arthrex supplemental response to Interrogatory No. 3) In FiberWire™, when

the UHMWPE is braided with PET, it is my opinion that the UHMWPE contributes to the strength of the overall heterogeneous braid. Further, UHMWPE is known to have relatively high lubricity and has different lubricity than PET.

64. My opinion is further supported by the testimony and documents from Arthrex and Pearsalls witnesses:

> Q What did you understand Mr. Grafton to mean when he said:
> "Can you build a 25% Dyneema/75% polyester blend in Size 2 that is very flexible".
> What did you understand that to mean?
> A Yes, that he wanted a braid which was more -- not so stiff.
> Q As the 100% ultra high molecular weight polyethylene?
> A Yes. (Hallet 1/12/06 Dep. at p. 306:20-307:4, DMI Ex. 324)

> Q. Mr. Grafton wanted Pearsalls to braid polyester with the ultra high molecular weight polyethylene so that the polyester could provide flexibility?
> A Yes. (Hallet Dep. at p. 307:10-14, DMI Ex. 324)

65. It is my expert opinion that both of the above documents and testimony demonstrate that Arthrex is "tailor[ing] the physical" properties of the braid by "varying the type and proportion of each of the dissimilar fiber forming materials used" as taught by the '446 Patent (Tab D at 2:58-61).

66. In summary, if it is determined that PE is not PE (does not include UHMWPE), it is my opinion that the ultra high molecular weight polyethylene in Arthrex's FiberWire™ and TigerWire™ suture products is equivalent to the claimed PE because it performs the same function, in the same way to achieve the same result. Any differences are insubstantial in the context of the invention.

VI. Opinions Regarding Contributory Infringement

67. I understand that contributory infringement is defined in 35 U.S.C. §271(c), which provides:

> Whoever offers to sell or sells within the United States or imports into the United States a component of a Patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a Patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

68. I understand that an act of actual direct infringement is necessary for a finding of contributory infringement. If there is direct infringement, then there is contributory infringement if the remaining requirements of the statute are satisfied.

69. I have been asked to provide my opinion as to whether Pearsalls has sold within the United States or imported into the United States a component of a patented suture that constitutes a material part of the invention in claims 1, 2, 8, 9 and 12 of the '446 patent. It is my opinion that Pearsalls has sold within the United States or imported into the United States a component of a patented suture constituting a material part of the invention in claims 1, 2, 8, 9 and 12 of the '446 patent.

70. It is my understanding that Pearsalls makes all of the braids used in Arthrex's FiberWire™ and TigerWire™ suture products. (Arthrex's Response to Mitek Interrogatory #2). Pearsalls imports into the United States unsterile, FiberWire™ and TigerWire™ suture that has not been cut to length or tipped. I personally observed the Pearsalls braided product at the final inspection stage before shipment. Pearsalls also sells within the United States this unsterile, FiberWire™ and TigerWire™ suture to R.K. Manufacturing (Ponton Dep. at p. 17:23-18:12).

71. It is my opinion that the unsterile FiberWire™ and TigerWire™ that Pearsalls imports and sells is a component of the invention of claims 1, 2, 8, 9 and 12 of the '446 Patent. The imported and sold FiberWire™ and TigerWire™ has the same construction as that sold by Arthrex except for some processing operations such as tipping, attachment to anchors or needles, and sterilization. (Ponton Dep. at p. 18:18-21). Thus, the imported and sold FiberWire™ and TigerWire™ has all of the limitations of claims 1, 2, 8, 9, and 12 except that it is not sterilized. It has a braid construction of polyethylene and PET in direct intertwining contact. Further, each has a core except for size 4-0 FiberWire™. Thus, the FiberWire™ and TigerWire™ that is sold and imported by Pearsalls is a component of the claims of 1, 2, 8, 9, and 12 and a material part of the invention of claims 1, 2, 8, 9, and 12.

72. I have been asked to provide my opinion as to whether the FiberWire™ and TigerWire™ imported and sold by Pearsalls is especially adapted for use for infringement of claims 1, 2, 8, 9, and 12 of the '446 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use. It is my opinion that the FiberWire™ and TigerWire™ imported and sold by Pearsalls is especially adapted for use in an infringement of the '446 Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use. The '446 Patent claims a suture. It is my understanding that RK Manufacturing does nothing to alter the FiberWire™ and TigerWire™ surgical braid. (Ponton Dep. at p. 18:18-21). The FiberWire™ and TigerWire™ imported and sold by Pearsalls has no known use other than as a suture, which is claimed in the '446 Patent. Thus, the FiberWire™ and TigerWire™ that is imported and sold by Arthrex is not a staple article of commerce and has no known substantial noninfringing use other than that that has been identified. (Pearsalls' Answers to Mitek's First Set of Interrogatories).

VII. Other Issues

73. It is my opinion that some of the benefits of FiberWire™ and TigerWire™ that are marketed by Arthrex are due to the patented invention, a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the heterogeneous non-bioabsorbable braid.

74. For example, Arthrex markets that FiberWire™ has superior strength, increased stiffness, and has been "enthusiastically endorse[d]" for "its feel." (DMI Ex. 7 at 2). FiberWire™'s and TigerWire™'s ultra high molecular weight polyethylene braided yarns contribute to FiberWire™ and TigerWire™'s strength and stiffness (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 267). Further, FiberWire™'s and TigerWire™'s PET contributes to the flexibility of the braid (DMI Ex. 324). Notably, the patented invention of claims 1, 2, 8, 9, and 12 includes a heterogeneous braid of PE and PET. Further, the '446 patent explains that a heterogeneous braid of dissimilar materials in direct intertwining contact can contribute to the overall properties of the heterogeneous braid (Tab D at 2:50-52; 3:43-48). Further, the '446 patent teaches that the braided yarns can be tailored in type and amounts to obtain the properties of each (Tab D at 2:58-61). FiberWire™ and TigerWire™ do just that by braiding polyethylene and PET. Thus, it is my opinion that benefits touted by Arthrex are due to the patented invention.

75. Arthrex's and Pearsalls' development of FiberWire™ and TigerWire™ confirms my opinion. For example, Mr. Hallet testified that in the development of FiberWire™ he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of

UHWMPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

76. It is my opinion that the braiding of dissimilar materials in direct intertwining contact in FiberWire™ contributes to the properties advertised by Arthrex in its marketing literature. For example, Arthrex has marketed that "that FiberWire™ is a "Braided Polyblend Suture" that it is "revolutionizing Orthopaedic Surgery" (DMI Ex. 7 at 1). I also note that Arthrex's claims that its FiberWire™ heterogeneous braid has superior properties is supported by "multiple scientific publications" (DMI Ex. 7 at 2). Thus, Arthrex is highlighting the braiding of dissimilar materials as claimed in claims 1, 2, 8, 9, and 12 of the '446 Patent.

77. Further, Arthrex has made many assertions that FiberWire™'s heterogeneous braid is superior to Ethibond's homogeneous braid. For example, Arthrex claims that the FiberWire™ is "twice as strong" as "polyester suture" (DMI Ex. 9 at 2; DMI Ex. 10 at 2; *see also* DMI Ex. 11; DMI Ex. 24 at ARM001473). Arthrex also asserts that "FiberWire™ has twice the strength of the similar *sized generic suture* with superior feel, tie ability, and lower knot profile" (DMI Ex. 13; emphasis added). Arthrex claims that its studies show that FiberWire™ has better knot strength than "Ethibond Excel braided polyester suture" (ARM002177-8; ARM002181-83; ARM002188-2191). It is my opinion that the braiding of polyethylene and PET in direct intertwining contact contributes to FiberWire™'s properties of strength and flexibility that Arthrex markets with respect to Ethibond.

78. At trial, I may use demonstrative exhibits. For example, I may use demonstrative exhibits to explain the design and construction of Arthrex's FiberWire™ and TigerWire™ suture products, to explain infringement, and to explain the other opinions that I have set forth in my report.

Dated: March 3, 2006

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

Rebuttal Expert Report of Dr. David Brookstein

I. Background Information

1. I previously submitted an expert report in this case on March 3, 2006. I have been asked to opine on certain opinions expressed by Dr. Mukherjee in his report entitled the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters."

2. I have reviewed the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters," the documents referenced in my prior report and those listed in Ex. H attached hereto.

II. Summary of Opinions

3. I disagree with Dr. Mukherjee's opinion that there is no infringement under the doctrine of equivalents, if "PE," as used in the claims of the 446 Patent, is construed not to include UHMWPE.

4. If Dr. Mukherjee is correct regarding the meaning of "consisting essentially of" and the novel and basic characteristics of the invention, it is my opinion that FiberWire's coating does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

5. If Dr. Mukherjee is correct regarding the meaning of "consisting essentially of" and the novel and basic characteristics of the invention, it is my opinion that the nylon in TigerWire does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

6. If Dr. Mukherjee is correct regarding the meaning of "consisting essentially of" and the novel and basic characteristics of the invention, it is my opinion that FiberStick's adhesive does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

7. The reverse doctrine of equivalents does not prevent infringement.

8. I disagree with Dr. Mukherjee that FiberWire's benefits, which Arthrex promotes, are almost exclusively due to the UHMWPE in FiberWire.

III. If PE Is Construed Not to Include UHMWPE, FiberWire Still Infringes Under the Doctrine of Equivalents

9. As I explained in my previous report, if "PE" as claimed in the 446 Patent is construed not to include "UHMWPE," there is infringement under the doctrine of equivalents because the differences between UHMWPE and "PE" are insubstantial. Dr. Mukherjee has expressed opinions to the contrary. But I disagree with him for at least the following reasons.

10. As one basis for his opinion of substantial differences between "PE" and UHMWPE, Dr. Mukherjee opines that the 446 Patent describes the first fiber-forming materials as "lubricous but relatively weak" and alleges that the first fiber-forming materials are different than UHMWPE, which is known to have certain strength properties (Mukherjee Res. Report at 15). I disagree because the 446 Patent does not describe the first fiber forming materials as "lubricous but relatively weak." In fact, it never describes the first fiber-forming materials, including "PE," as

"weak." Rather, in a preferred embodiment, the 446 Patent describes the first fiber-forming materials as acting "as lubricating yarns," but not "weak" yarns (Ex. D at 4:11-12). UHMWPE is consistent with the description of the first fiber-forming materials in the 446 Patent. The 446 Patent describes that, in a preferred embodiment, the first yarns act as lubricating yarns (Ex. D at 4:11-12). PE, including UHMWPE, is a lubricious material (Ex. I at 52:24-53:1). Further, the 446 Patent explains that the first set of yarns may be "non-absorbable polymers" (Ex. D at 4:10-11). UHMWPE is a non-absorbable polymer. The 446 Patent also describes the first set of yarns as being made from fiber-forming materials (Ex. D at 2:45-46). UHMWPE is a fiber-forming material. Therefore, the 446 Patent's description of the first-fiber forming materials is consistent with UHMWPE. Moreover, UHMWPE is consistent with the more general description of the invention, as set forth in column 2, lines 40-63, column 3, lines, 21-28, 40-65, and column 6, lines 50-56. Therefore, I disagree with Dr. Mukherjee's opinion that the 446 Patent describes the first fiber-forming materials as "weak," and I also disagree that the differences between UHMWPE and PE are substantial.

12. I disagree that the 446 patent describes the first fiber-forming materials as "weak," as Dr. Mukherjee states (Mukherjee Res. Report at 15), for additional reasons. Dr. Mukherjee states that the 446 Patent describes the first fiber-forming materials as being "weak." But this is incorrect. For example, the 446 Patent describes PE, which includes UHMWPE, as a first fiber-forming material, and UHMWPE was known to have certain strength attributes, such as tensile strength. Likewise, the 446 Patent describes polypropylene (PP) as a first fiber-forming material, and it is known to have certain strength attributes, namely tensile strength. This is described in the literature. For example, *Marks' Standard Handbook for Mechanical Engineers*, a well known reference, describes polypropylene fibers as having a breaking tenacity of 4.0-7.0 gpd

(Ex. J). Further, U.S. Patent No. 4,413,110 describes certain polypropylene fibers as having a tenacity of at least about 8 gpd (Ex. K at 2:7-11). Also, the *Production and Applications of Polypropylene Textiles* states on page 54 that the breaking tenacity of polypropylene fibers is over 500 $mNtex^{-1}$ (Ex. L). Thus, certain polyethylene and polypropylene fibers are not "weak" in tensile strength. Thus, I disagree with Dr. Mukherjee's statement that the first-fiber forming materials are all "weak."

13. Dr. Mukherjee seems to indicate that the first fiber-forming materials are all necessarily "weak" in tension when compared to the second fiber-forming materials. But this is incorrect because polypropylene fibers, one of the first fiber-forming fibers, were known to have strength on the same order of magnitude of nylon and PET fibers, two of the second fiber-forming materials. For example, *Marks' Handbook* describes polyester fibers, which I read as including PET, as having a breaking tenacity of 4.4-7.8 gpd, and nylon 6,6 fibers as having a breaking tenacity of 4.6-9.2 gpd (Ex. J). Further, the *Production and Applications of Polypropylene Textiles* states on page 54 states that the breaking tenacity of polyester fibers, which I read as including PET, is 350 $mNtex^{-1}$ (Ex. L). Using this information, PP has a breaking tenacity in the range of other well known relatively high-strength fibers such as polyester (PET) and nylon. Further, one fiber manufacturer describers the tensile strength of two first fiber-forming materials, PVDF and PP, as having about the same tensile strength as two of the second fiber-forming materials, nylon and PET. For example, it states that monofilament PVDF has a tenacity of 4.71 gpd, two monofilament polypropylenes have breaking strengths of 3.0 and 4.0 gpd, two monofilament polyesters (which I read as PET) as having a breaking strength of 4.5 or 6.0 gpd, and nylon monofilaments as having a breaking strength of 4.5-6 gpd (Ex. M; see also Ex. N). Consequently, the first fiber-forming materials are not all "weak" in tension in

comparison to the second fiber-forming yarns, and I disagree with Dr. Mukherjee's assertion that they are.

14. As another basis for his opinion of substantial differences, Dr. Mukherjee opines that the differences between the claimed "PE" (if PE does not include UHMWPE) and UHMWPE are substantial because the claimed second fiber-forming materials are "added for strength" and UHMWPE is added to increase FiberWire's strength. I understand that the relevant comparison is between PE and UHMWPE, not between the claimed second fiber-forming materials and UHMWPE. Thus, I am not sure why Dr. Mukherjee is comparing the second fiber-forming materials to UHMWPE. Nevertheless, I disagree with his statement that FiberWire's construction is the opposite of what is described in the 446 Patent. The 446 Patent describes embodiments in which the first set of yarns is lubricous and provides PE as an example of a lubricous yarn (Ex. D at 4:11-12). The UHMW PE in FiberWire is consistent with this description; FiberWire's UHMW PE is lubricous (Ex. I at 52:24-53:1). The 446 Patent also describes embodiments in which the claimed second fiber-forming yarns, including PET, are braided with the claimed first fiber-forming lubricous yarns, including PE, "to provide improved strength to the heterogeneous braid" (Ex. D at 4:33-36). FiberWire is consistent with this description; FiberWire's PET has a different lubricity than UHMWPE and adds improved strength to the FiberWire braid (Ex. I at 53:20-54:5; 46:16-47:5). Accordingly, PET increases certain knot strength properties, namely knot holding strength,[1] of the braid of PET and UHMWPE because it reduces the tendency of the UHMWPE fibers to slip when tied in a knot.

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[1] I use the term "knot pull strength" to refer to the force at which a suture having a knot tied in it fails when tested in a tension test (*see, e.g.,* Ex. O). I use the term "knot holding strength" to refer to the force at which a knot fails by slipping, elongating to a certain extent, or breaking, which can be tested generally in a procedure similar to Ex. P, Q. Knot holding strength is an indication of knot security. The 446 Patent describes another exemplary knot security test (Ex. D at 6:36-44).

Thus, because FiberWire's UHMWPE is lubricous and FiberWire's PET imparts strength, FiberWire's construction is not the opposite of that described and claimed in the 446 Patent. Rather, it is consistent with the 446 Patent's teachings.

15. My opinion is supported by Mr. Grafton's testimony regarding the development of FiberWire and by Arthrex's 234 patent. As Mr. Grafton explained, he had developed a suture having a homogeneous braid of UHMWPE (Ex. I at 51:15-17). But he found this UHMWPE braid to be unacceptable because it had poor knot holding strength properties (Ex. I at 45:16-46:15; 50:1-53:7). As Mr. Grafton explained, the poor knot holding strength properties were attributable to UHMWPE being a lubricous material, which causes the knot to slip (Ex. I at 52:24-53:7). To increase the knot holding strength, Mr. Grafton braided UHMWPE with PET (Ex. I at 53:20-54:5; 46:16-47:5). Mr. Grafton tested the UHMWPE and PET braid and found that it had improved knot holding strength properties as compared to the UHMWPE braid (*i.e.*, the heterogeneous braid did not slip like the homogeneous UHMWPE braid) (Ex. I at 54:24-55:1). This type of UHMWPE and PET braid ultimately became FiberWire. Thus, as Mr. Grafton's experience shows, FiberWire is a braid of UHMWPE (a lubricous yarn) with PET, and the PET increases the knot holding strength of the braid. Accordingly, FiberWire's braid is not, as Dr. Mukherjee opines, the opposite of what is described in the 446 Patent.

16. Arthrex's 234 Patent also supports my opinion. According to Mr. Grafton's 234 Patent, UHMWPE, "while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. R at 1:19-21; Ex. I at 104:9-15). Mr. Grafton defines knot tie down as a strength, namely the "ability to approximate the tissue and hold [tissue] in place through biomechanical forces" in the body (Ex. I at 26:24-27:2). Mr. Grafton's definition of knot tie down is part of what I refer to as knot holding strength.

According to Arthrex's 234 patent, this problem was overcome by braiding UHMWPE with polyester (Ex. R at 2:50-57). As the 234 patent explains, braiding polyester with UHMWPE improves knot tie down characteristics or the "ability to approximate the tissue and hold it in place through biomechanical forces" (Ex. I at 26:24-27:10). Thus, the 234 patent teaches that polyester, which includes materials such as PET, imparts knot tie down or knot holding strength to a braid of UHMWPE and polyester.

17. Dr. Mukherjee further opines that the differences are allegedly substantial between "PE" (if PE does not mean UHMWPE) and UHMWPE, as used in FiberWire, because UHMWPE is what makes FiberWire so strong (Mukherjee Res. Report at 16). I disagree. As explained above, although one might expect that UHMWPE provides certain strength attributes to FiberWire, namely, tensile strength, the PET adds certain strength characteristics as well, including knot holding strength. Notably, Arthrex discarded the idea of using a braid of just UHMWPE because it had poor knot holding strength characteristics, and braided PET with UHMWPE to increase the knot holding strength.

18. In support of his opinion regarding substantial differences, Dr. Mukherjee also performs a function/way/result analysis. I also disagree with this analysis. Dr. Mukherjee states that the "function" performed by the claimed first fiber-forming materials is "to add lubricity with the recognition that these materials will detract from the strength of the resulting suture" (Mukherjee Res. Report at 16). I disagree. The 446 Patent does not describe the function of the claimed first-fiber forming materials as "detract[ing] from strength." I disagree with Dr. Mukherjee's opinions regarding "detract[ing] from strength" for the same reasons that I stated above with reference to his opinions that the 446 Patent describes the first-fiber forming materials as "weak." Further, I disagree that his reference to column 4, lines 42-54, and a

variation of a single embodiment of a PTFE/PET braid is a statement that the first fiber-forming materials are "too weak for most suture applications" (Mukherjee Res. Report at 7). This section of the 446 Patent describes variations of single embodiment and does not discuss the use of the first fiber-forming materials in "most suture applications."

19. Nevertheless, even if Dr. Mukherjee is correct about the "function" of the claimed first fiber-forming materials, UHMWPE, as used in FiberWire, performs the function of adding "lubricity with the recognition that these materials will detract from the strength of the resulting suture." UHMWPE is a lubricous material that adds lubricity to the FiberWire braid (Ex. I at 52:24-53:1). Also, it is recognized that UHMWPE, due to its lubricity, detracts from certain strength characteristics, including knot holding strength (*see above*, Ex. R at 1:19-21; Ex. I at 104:9-15).

20. Although Dr. Mukherjee refers to the "way" and the "result" of the claimed first fiber-forming material, he never defines what they are. For example, Dr. Mukherjee states that the "result obtained by substituting UHMWPE for the first fiber-forming materials is substantially different." But he does not provide his opinion regarding the "result" attributable to the claimed first fiber-forming materials and the "way" the first-fiber forming materials perform their function. Nevertheless, I disagree with his opinion that the "result" of using UHMWPE in FiberWire is limited to increasing strength. It also adds lubricity which enhances other FiberWire properties such as handleability. Also, he seems to attribute all of FiberWire's strength properties to UHMWPE. I disagree with this opinion. PET also contributes to FiberWire's strength properties, namely knot holding strength properties (Ex. R at 1:19-21,29; 2:50-52; Ex. I at 104:9-15). Further, even if FiberWire's function is increasing tensile strength,

it is my opinion that the first fiber forming materials, such as PP, function to add tensile strength. Therefore, the differences are insubstantial.

21. Dr. Mukherjee disagrees with my opinion regarding equivalents because it is too broad. I believe that he misunderstands my opinion. My equivalency opinion is limited to nonbioabsorbable yarns as the first-forming material.

IV. Under Dr. Mukherjee's Definition of "Consisting Essentially Of," FiberWire Infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent

22. As I understand the law, because the 446 Patent claims recite the phrase "consisting essentially of," if FiberWire has structure in addition to the structure listed in the 446 Patent claims, there is infringement, unless the additional structure materially affects the "basic and novel characteristics" of the claimed suture. Dr. Mukherjee opines that the "basic and novel characteristics" of the suture claimed in the 446 Patent are "a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Mukherjee Res. Report at 18, Section VI.D.). According to Dr. Mukherjee, FiberWire's coating, TigerWire's nylon visual marker strand, and FiberStick's adhesive, each provide a "material" affect on this novel and basic characteristic that precludes infringement (Mukherjee Res. Report at 22, 30, 31). I disagree with Dr. Mukherjee's opinion and address each of his three points below.[2]

[2] Mr. Grafton's testimony and Arthrex's 234 patent support my opinion regarding the equivalence of UHWMPE and PE if "PE" is defined not to include UHMWPE as well as my opinion that there is no material affect on the novel and basic characteristics as set forth in my previous report for the reasons set forth herein. For example, they show that the differences are insubstantial because UHMWPE provides lubricity and PET provides knot holding strength.

A. If the Novel And Basic Characteristics Have The Definitions Provided By Dr. Mukherjee, FiberWire's Coating Does Not Materially Affect Them

23. According to Dr. Mukherjee, the novel and basic characteristics are "a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Mukherjee Res. Report at 18). Dr. Mukherjee opines that FiberWire's coating materially affects this novel and basic characteristic. I disagree for the following three reasons: (i) FiberWire was specifically engineered to have the properties described in the 446 Patent; (ii) the 446 Patent does not consider coating of the type used on FiberWire to have a "material" affect on the basic and novel characteristics; and (iii) Dr. Mukherjee's tests are flawed or inconclusive. I describe each of these three points below.

1. FiberWire Was Engineered to Have The Basic and Novel Characteristics, and the Coating Does Not Materially Affect Them

24. FiberWire's coating does not materially affect FiberWire's characteristics of having two dissimilar yarns (*i.e.*, UHMWPE and PET) braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. Both before and after the coating is applied to FiberWire, FiberWire has two dissimilar yarns (*i.e.*, UHMWPE and PET). Further, regardless of the coating, the UHMWPE and PET braid provides improved handleability and pliability performance without significantly sacrificing physical properties. The coating does not prevent or materially affect the two materials from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words because FiberWire still obtains the handleability/physical property benefits of the UHMWPE/PET braid after the coating is applied, the coating does not materially affect the novel and basic characteristics. FiberWire's coating is merely a surface "lubricant" (Mukherjee Res. Report at Ex. 16).

25. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by Arthrex's development and testing of FiberWire. Arthrex and Pearsalls had originally developed a suture having a homogeneous 100% UHMWPE braid. But they found it to have unacceptable knot holding strength properties (Ex. I at 52:24-53:7). The homogeneous UHMWPE braid was too lubricous to "hold a knot" (Ex. I at 45:16-46:15; 50:1-53:7). At the same time, Arthrex found that the same braided UHMWPE suture had other good "strength" properties (Ex. I at 46:7-8). I consulted with Dr. Hermes and, based on his opinion and because UHMWPE fibers are lubricous (Ex. I at 52:24-53:1), the UHMWPE braid would also have had some good handling properties including surface frictional properties, such as tactile feel. Also, the lubricous yarns would contribute to braid pliability because they allow the fibers to slide past each other when bent. Arthrex and Pearsalls also developed sutures having homogeneous polyester braids (Ex. S). According to Mr. Grafton, Arthrex found them to have lower knot pull strength than a braid of UHMWPE fibers and polyester fibers (Ex. S; Ex. I at 81:8-12). Thus, Arthrex thought that sutures having braids of UHMWPE and braids of polyester each had different drawbacks. Ultimately, Mr. Grafton braided UHMWPE with PET, which is a polyester, and found that the heterogeneous braid had improved knot holding strength properties; it did not slip like the UHMWPE braid he had made:

Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to

reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?
A. I've lost count, it's been so many times, but the answer again is yes.

(Ex. I at 53:2-54:5) (objections omitted). This type of UHMWPE and PET braid was ultimately marketed as FiberWire. Thus, Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (Ex. I at 68:25-70:13). For example, UHMWPE in FiberWire's braid contributes to the braid's tensile strength, knot pull strength, pliablity, and lubricity/handling, and PET contributes to the braid's knot holding strength, and handling/pliability. Thus, Arthrex designed FiberWire to be braid of dissimilar yarns that has improved handleability and pliability performance without significantly sacrificing physical properties. Although FiberWire is coated, it is still a braid of dissimilar yarns having these benefits. Although the coating may enhance certain suture properties, the coating does not materially affect the fact that FiberWire has a braid with improved handleability and pliability performance without significantly sacrificing physical properties.

26. My opinion that FiberWire was specifically designed to have the novel and basic characteristics that Dr. Mukherjee attributes to the 446 Patent is further supported by other aspects of FiberWire's development. For example, during FiberWire's initial development, Mr.

Grafton asked Pearsalls to "build a 25% Dyneema/75% polyester *blend* in a size 2 that is *very flexible* (like the existing suture or the Ethicon sample)" (Ex. HH) (emphasis added). As Mr. Grafton stated, "[i]f we can get this blend correct, we will have a terrific advancement" (Ex. HH). According to Mr. Grafton, Arthrex varied the dissimilar braid materials in type and amount in order to optimize FiberWire's properties:

Q. I would like to know what you mean by in your letter when you said, "If we can get this blend correct." You asked them for a 25 percent Dyneema/75 percent polyester blend in Size 2 that's very flexible. And then you said, "If we can get this blend correct, we will have a terrific advancement." What did you mean by "If we can get this blend correct"?
A. The optimization of the two materials. If you had the knot strength, loop security, and tensile strength, as well as the tactile feel of the suture all superior to what was on the market, then it would be a superior product.
Q. Wait a second. You said optimization of two materials.
A. (Witness nods head affirmatively).
Q. At this point in time, November 1998, were you trying to vary the amount and type of the Dyneema and polyester in the braid in order to get the best properties?
A. During -- during the -- during that period of time, yes.
Q. So you were balancing off the properties of each material to try to get the optimum properties --
A. Tensile strength.
Q. To get the optimum tensile strength?
A. (Witness nods head affirmatively).
Q. What about knot security?
A. Yes.
Q. Okay. So you were varying the amount and type of the materials to get the optimum knot security, optimum tensile strength?
A. Yes.
Q. Any other properties? Knot tiedown?
A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.
Q. So you were varying type and proportion of the

materials to optimize all these properties in the product?
A. Yes.

(Ex. I at 68:25-70:13). Further, as explained by Ms. Holloway, FiberWire was braided, so that the individual materials contribute to FiberWire's handleability:

Q. What materials contribute to the handleability of Arthrex's FiberWire sutures?
A. All materials used.

(Ex. T at 31:23-25). Thus, in designing FiberWire to have a dissimilar yarn braid, Arthrex specifically designed FiberWire to have the basic and novel characteristics that Dr. Mukherjee attributes to the 446 Patent: (i) a dissimilar yarn braid having the benefits of each yarn; and (ii) improved handleability and pliability without significantly sacrificing physical properties. Although FiberWire is coated, it still reaps the benefits of this dissimilar yarn braid in terms of handleability/pliability and physical properties. Therefore, the coating does not materially affect the novel and basic characteristics as defined by Dr. Mukherjee.

27. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is further supported by the fact that FiberWire has a very small amount of coating. In fact, it is so small that Pearsalls and Arthrex consider it unmeasureable (Ex. U at 119:5-9; Ex. V at 94:2-9; Ex. W at 48:1-50:16; Ex. X at ARM2104). I have personally observed and studied Pearsalls' coating processes for FiberWire during an inspection of Pearsalls' facilities in January 2006. FiberWire is coated by passing a braid of PET and UHMWPE, which has been dyed[3] and scoured, through a bath of NuSil Med 2174 polymer and Xylene solvent at a rate of 20 meters

[3] Most FiberWire is dyed blue. But some, such as TigerWire is not. Also, TigerWire has a braid that includes a Nylon marker band in place of one PET yarn.

per minute (Ex. U at 88:4-9; 82:14-18). Xylene is not a coating. Rather, Xylene is a solvent that dissolves the Med NuSil polymer, so that it can adhere to the FiberWire braid (Ex. U at 87:25-88:3; Video of Pearsalls' manufacturing). After passing through the solution, the coated FiberWire is passed through pads, which are compressed together, to wipe away excess coating (Ex. U at 97:1-18). Further, FiberWire is passed through a five-stage oven that dries the coating and evaporates the solvent (Ex. U at 95:14-17). The process is then repeated. I have measured the amount of coating by weight on FiberWire by determining the linear density (*i.e.*, grams/unit length) of a sample that was not coated, a sample that had been coated once, and sample that had been coated twice (DM Exhibits 284, 342, and 285). I determined that the linear density of Ex. 284 (uncoated) is 2393 denier, Ex. 342 (coated once) is 2474 denier, and Ex. 285 (coated twice) is 2508 denier using a traditional Mettler balance housed at the Philadelphia University Research Center Materials Evaluation Laboratory. Accordingly, the linear density of Ex. 342 indicates a 3.4% pick-up of coating material from the uncoated Ex. 284. The linear density of Ex. 285 indicates a 1.4% pick-up of additional coating material from Ex. 342. Thus, the total pick-up of Ex. 285 over Ex. 284 is approximately 4.8%. The result of this coating process is that, although FiberWire has a very small amount of coating, FiberWire still has two dissimilar yarns braided together to form a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words, the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided. For example, the coating is not applied in a very thick layer and then melted together with the yarns to form a non-braided structure. As Arthrex explains in its instructions for use, FiberWire's coating is just a "lubricant" (Mukherjee Res. Report at Ex. 16).

28. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by both my visual observations of FiberWire, as well as those by CETR. Both my photographs and CETR's show that, even at extreme magnifications, it is difficult to even see coating in certain areas of the suture. In fact, both sets of pictures show that FiberWire has fibers that retain their morphological attributes, so that they can contribute to the handleability, pliability, and physical properties of FiberWire.

29. Dr. Mukherjee opines that the SEM's attached to my expert report are "too unclear to draw any conclusions from them" (Mukherjee Res. Report at 30). But Dr. Mukherjee concludes based on these SEM's that the "coating has permeated into the braid" (Mukherjee Res. Report at 30). I do not understand how Dr. Mukherjee can say the SEM's are "too unclear to draw any conclusions" then make conclusions from the very same "unclear" micrographs.

30. I note that Dr. Mukherjee does not opine on the issue of whether FiberWire's coating materially affects the fact that it has a dissimilar yarn braid with improved handleability and pliability without significantly sacrificing physical properties. Rather, he seems to opine that FiberWire's coating affects certain individual properties. But that is not the relevant issue even as he defined the novel and basic characteristics. Rather, the relevant issue as he framed it was whether FiberWire's coating materially affected FiberWire from being a suture with "two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Mukherjee Res. Report at 18). In my opinion, because FiberWire is specifically designed to have precisely these characteristics and its

coating is essentially a surface lubricant, FiberWire's coatings effects are not material to the novel and basic characteristics.

2. Based on the 446 Patent, FiberWire's Coating Does Not Materially Affect the Novel and Basic Characteristic

31. In order to determine whether an effect on the basic and novel characteristics, as those terms are defined by Dr. Mukherjee, is "material," I have consulted the 446 Patent to determine what it considers "material" or not "material." In other words, I have considered whether FiberWire's coating is "material" in the context of the invention described in the 446 Patent. Based on the 446 Patent's description of the invention and its description of coatings, FiberWire's coating does not "materially" affect the novel and basic characteristics, as defined by Dr. Mukherjee.

32. My opinion that FiberWire's coating does not have a "material" effect is based on the 446 Patent's explanation that "coating" is not "material" to the invention. As the 446 Patent explains, the direct intertwining braid of dissimilar materials provides "outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. D at 2:50-52). The 446 Patent further explains that such a braid can be further improved with a coating (Ex. D at 6:5-21). Thus, because the 446 Patent specifically contemplates applying coatings of the type used in FiberWire to refine certain braid properties, the 446 Patent does not consider coatings, of the type applied to FiberWire, to have a "material" effect on the basic and novel characteristics of the suture claimed in the 446 Patent.

33. I disagree with Dr. Mukherjee's opinion that FiberWire's coating has a "material" effect because he basically *excludes* coated sutures from the 446 Patent claims (Mukherjee Res. Report at 22). But this is just contrary to the teachings of the 446 Patent. As the 446 Patent describes, the inventors specifically contemplated preferred embodiments having coatings:

> If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to ***further*** improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. ***Most preferably***, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating ***may be*** eliminated saving expense as well as avoiding the associated braid stiffening.

(Ex. D at 6:5-18) (emphasis added). Thus, the inventors specifically *included* coatings within the description of the invention, not *excluded* them, as Dr. Mukherjee opines. Therefore, because the 446 Patent specifically contemplated coatings, such as that used in FiberWire, it is my opinion that FiberWire's coating cannot be deemed to have a "material" effect on the basic and novel characteristics of the invention.

34. My opinion that FiberWire's "coating" does not have a "material" effect is further supported by the fact that Arthrex and Pearsalls did precisely what the 446 Patent teaches to obtain the basic and novel characteristics that Dr. Mukherjee attributes to the suture claimed in the 446 Patent. The 446 Patent teaches forming a heterogeneous braid which has a first and a second set of continuous and discrete yarns (Ex. D at 2:40-41). FiberWire's UHMWPE and PET are braided in a heterogeneous braid and are continuous and discrete yarns. The 446 Patent teaches braiding a lubricous yarn with a yarn of different lubricity (Ex. D at 4:11-12; 4:33-40). Arthrex and Pearsalls do that; they braid UHMWPE, a lubricous yarn, with PET, a yarn of different lubricity. The 446 Patent teaches braiding dissimilar yarns in direct intertwining contact (Ex. D at 2:43-44). Arthrex and Pearsalls braided PET and UHMWPE yarns in direct intertwining contact (Ex. V at 107:5-8). The 446 Patent teaches that each yarn has a plurality of filaments (Ex. D at 2:45-48). FiberWire's braided UHMWPE and PET yarns each have a plurality of filaments, as shown in Exs. E-G attached to my first report and CETR's images. The 446 Patent teaches braiding yarns to obtain the benefits of each. Arthrex and Pearsalls do that as

is shown by its product development (Ex. I at 68:25-70:15). The 446 Patent teaches "to tailor" the physical braid properties "by varying the type and proportion of each of the dissimilar fiber forming materials used" (Ex. D at 2:59-61). Arthrex did just that by trying different types and amounts of UHMWPE and polyester (Ex. I at 68:25-70:15). The 446 Patent teaches coating the braid by immersing it in a solution of a coating polymer and a solvent (Ex. D at 6:9-10). Likewise, Pearsalls and Arthrex coat by passing FiberWire through a coating solution (see above). The 446 Patent specifically contemplates that coating can "***further***" improve the handleability of the suture (Ex. D at 6:5-18) (emphasis added). According to Dr. Mukherjee, FiberWire's coating further improves handleability (Mukherjee Res. Report at 22-23). The 446 Patent states a preference that coating does not adhere the yarns or fibers to one another thereby increasing stiffness (Ex. D at 6:11-13). As shown by the SEM's of the FiberWire, the fibers are not bonded together (Mukherjee Res. Report at Ex. 20 and Exs. E-G). Thus, because Arthrex and Pearsalls specifically engineered FiberWire to be a nonabsorbable heterogeneous braid, as is precisely described in the 446 Patent, the effects of FiberWire coating can hardly be considered material.

35. I further disagree with Dr. Mukherjee's focus on FiberWire's coating with reference to defining what is "material" because the 446 Patent is not about "coating" or eliminating "coatings." Rather, the problem addressed by the 446 Patent is how to improve multifilament braided suture properties. For example, the 446 Patent explains that some prior art attempted to improve braided multifilament suture properties at the expense of restricting the movement of adjacent filaments (Ex. D at 1:26-29). The 446 Patent then provides some prior art attempts including a certain polyester coating for multifilament sutures (Ex. D at 1:32-43), a PTFE coating (Ex. D at 1:43-54), a monofilament like surface on a multifilament braid (Ex. D at 1:55-

3:2), and an elongated core (Ex. D at 2:3-13). According to the 446 Patent, these techniques could be improved upon because they did not focus on improving multifilament properties by increasing fiber-to-fiber mobility (Ex. D at 2:14-17). Thus, the 446 Patent is not saying that coating was a problem that had to be solved. Rather, the 446 Patent is teaching that certain coatings and other techniques were insufficient *by themselves* to sufficiently improve certain multifilament suture properties.

36. As a solution to the issue of improving multifilament braided suture properties, the 446 Patent teaches braiding dissimilar fiber-forming materials in direct intertwining contact to form a heterogeneous braid, that has properties "attributable to the specific properties of the dissimilar fiber-forming materials" (Ex. D at 2:40-53). The 446 Patent also states that certain properties of the dissimilar yarn braid can be "improved" by a coating (Ex. D at 6:5-21). Thus, the solution to the issue of improving multifilament braid properties provided by the 446 Patent is to braid dissimilar fiber-forming yarns in direct intertwining contact. Thus, coatings were not material to the issue addressed by the 446 Patent, nor the solution provided. Therefore, the 446 Patent's description of the invention shows that it does not consider coating, as used on FiberWire, to have a "material" effect on the basic and novel characteristics of the claimed suture.

3. To The Extent That I Understand Dr. Mukherjee's Tests, They Are Irrelevant or Inconclusive

a) Dr. Mukherjee's Tests Are Irrelevant

37. I note that Dr. Mukherjee opines that "coating materially affects handleability," "knot security and knot strength" (Mukherjee Res. Report at 22 and 27). But he never opines on whether the coating materially affects the basic and novel characteristic that he attributes to the 446 Patent, namely two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. According to Dr.

Mukherjee, FiberWire's coating affects certain individual suture properties. But the novel and basic characteristics that he attributes are not just individual suture properties. Rather, they are the benefits of braiding dissimilar yarns to improve one property (*e.g.*, handleability) without significantly sacrificing others (*e.g.*, physical properties). As explained above, FiberWire's braided construction has these benefits. Accordingly, any purported affect by FiberWire's coating cannot be considered material in the context of the invention.

38. Dr. Mukherjee seems to rely on the 446 Patent's statement about preferred embodiments for his rationale that a coating will materially affect the basic and novel characteristics of the invention. But he misstates the statement upon which he relies and therefore incorrectly defines material effects. The 446 Patent states that "in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional *homogeneous* fiber braids, without sacrificing physical strength or knot security" (Ex. D at 2:62-66) (emphasis added). Thus, the 446 Patent was discussing improved properties relative to *homogeneous* braids, not relative to *uncoated heterogeneous* braids of dissimilar yarns. Dr. Mukherjee ignores the reference to the homogeneous braid.

b) Dr. Mukherjee's Testing and Analysis Is Flawed

39. Dr. Mukherjee relies on Pearsalls' knot strength data (Mukherjee Res. Report Ex. 25), testing performed by Arthrex (Mukherjee Res. Report Ex. 19), testing performed by CETR (Mukherjee Res. Report Ex. 20), and "drape tests" performed by him and Dr. Burke (Mukherjee Res. Report at 27). I do not have sufficient information to fully analyze all of these tests. For example, I do not have information sufficient to determine whether the only difference between the tested samples was coating, how the samples were manufactured, the parameters of the test specifications, and whether the reported data was the complete data obtained from any and all tests performed. Nevertheless, I have formed opinions to the extent that I can, based on the

limited information with which I have been provided. Also, I note that CETR and Dr. Mukherjee appear to have analyzed and tested only FiberWire size #2 and appear to have applied that analysis without any explanation to all FiberWire products.

(1) Pearsalls' Knot Pull Strength Tests Show No Material Change in Knot Pull Strength

40. Dr. Mukherjee relies on Pearsalls' knot pull strength data summarized in Exhibit 25 to his Responsive Report for his opinion that FiberWire's coating materially affects FiberWire's knot pull strength (Mukherjee Res. Report at 28-29). Exhibit 25 to Dr. Mukherjee's Responsive Report is a listing of the average knot pull strength per batch at the "dye" and "measure" stages. Dr. Mukherjee concludes from this data that the coating causes knot pull strength to materially increase. As I understand the data, the "dye" column is the average knot pull strength of a FiberWire batch that did not undergo the coating process that I observed at Pearsalls, and the "measure" column is the average knot pull strength of FiberWire that underwent the coating processes (Ex. U at 47;1-23 Exs. Y and Z). This data appears to show that, in a significant number of instances, the measured knot pull strength *decreased* from the dye to the measure stage and therefore decreased after coating was applied to the suture. Also, at times, the measured knot pull strength stayed exactly the same. Thus, I do not know how Dr. Mukherjee can conclude from data, a significant amount of which is contradictory, that coating causes an increase in knot pull strength. He provides no explanation for this contradiction. Also, it is not clear why he necessarily attributes the change in knot pull strength to be due to coating. He fails to consider the inherent differences in tying knots, which can affect results, manufacturing differences between the "dye" and "measure" samples, and the known large variability in testing textile properties. Mr. Hallet from Pearsalls even explained that variations in the data, which Dr. Mukherjee relies upon, can be due to testing differences, not the material, and the variations in

the data were not really variations (Ex. U at 244:4-6; 348:22-349:6). To the extent that Dr. Mukherjee is relying on the final "average" computed in Ex. 25, that is improper.

41. I further disagree that Dr. Mukherjee can conclude from Pearsalls' knot pull strength data that FiberWire's coating materially affects FiberWire's knot pull strength (Mukherjee Res. Report at 28-29) because he ignores entire sections of relevant data. Pearsalls' normal practice is to perform knot pull strength testing at three stages of manufacturing, namely, the "dye," "intermediate," and "measure" stages. But Dr. Mukherjee wholly ignored the "intermediate" test stage data. The "intermediate" test stage data shows some of the flaws in his analysis. I understand that the suture that is tested during the "intermediate" and "measure" stage has not had any change in materials or undergone different processing (Ex. U at 348:5-13). Therefore, the knot pull strength should not change for a given batch between the "intermediate" and the "measure" stages. But, as summarized in Exhibit AA, Pearsalls' testing shows that the measured knot pull strength was generally not the same at the intermediate and measure stages. Because Pearsalls measured "differences" in knot pull strength between the "intermediate" and "measure" stages, when one would have expected it to stay the same, it would not be correct to conclude that there was in fact a change in knot pull strength between the "intermediate" and "measure" stages. Likewise, absent some explanation, it is not correct to conclude that the knot pull strength is "changing" between the "dye" and "measure" stages. Rather, Pearsalls' tests show that the knot pull strength basically stays the same before and after coating and that variations are probably due to testing differences, such as how the knot was tied. In fact, Mr. Hallet was asked why, for some batches, the average knot pull strength stayed about the same between the "dye" and "measure" stages, but went up at the "intermediate" stage (Ex. U at 341:16-344:25; Ex. BB). Mr. Hallet stated that the differences were probably due to the "operator" or the way the knot

was tied (Ex. U at 343:3-12). Also, Mr. Hallet testified that some changes were not really changes and were considered "about the same" (Ex. U at 344:22-25; Ex. CC). Further, when asked why, for one batch, the average knot pull strength went from 14.83 at the "intermediate" stage to "16.87" at the measure stage, Mr. Hallet attributed it to the "operator" (Ex. U at 346:21-347:1). Further, after reviewing the variations in some batches between the dye, intermediate, and measure stages, Mr. Hallet concluded that the data does not really show any variations in average knot pull strength:

> Q Well, if you look at the testing you cannot really say -- are they all within the tolerance of the testing so that you cannot really say that one of these values is greater than the other?
> A Yes.
> MR. BONELLA: That's correct
> A Yes.

(Ex. U at 348:22-349:6) (objection omitted). Thus, based on my review of Pearsalls' data and Mr. Hallet's explanation of the source of the data, I disagree with Dr. Mukherjee's opinion that he can conclude from the data in Exhibit 25 to his report that FiberWire's coating increased FiberWire's knot pull strength. If anything, Pearsalls' data show that FiberWire's coating has no material effect on knot pull strength.

(2) Arthrex's "Knot Tiedown" Test Is Inconclusive

42. With respect to Arthrex's "knot tiedown" test (Mukherjee Res. Report at Ex. 19), I am unable to draw any definitive conclusions from these tests because Dr. Mukherjee has not provided information about specifically which samples were tested. Also, with respect to Arthrex's "knot tiedown" test, I believe the test is not proper for the reasons expressed by Dr. Hermes.

(3) CETR's Tests Are Flawed and Inconclusive

43. Dr. Mukherjee relies on the CETR tests. But the CETR report does not explain what was tested other than "two new spools of US 2 FiberWire sutures from the law firm, one coated and the other uncoated." Without further information about the construction, manufacturing, processing, and handling of the samples, I cannot completely comment on the CETR tests. Further, the testing methodology is not completely clear from the CETR report. Thus, I cannot fully comment on the tests that CETR conducted.

44. Even assuming that the only difference between the two tested samples is coating, the tests are also inconclusive for the following reasons. Dr. Mukherjee uses the CETR "pliability test" to determine the effect of coating on pliability. But the "pliability test" described in section 5 of the CETR report, and the data derived from this test, are flawed for at least three reasons: (i) the purported "pliability" test uses a *tensile* test to imply pliability; (ii) the "pliability" test incorrectly assumes that *multifilament* FiberWire acts as a *monofilament*; and (iii) the "pliability" assumes a circular cross-section and a constant diameter of the suture. I address each of these errors below.

45. The test described in section 5 of the CETR report is a *tensile* test in which the FiberWire samples were not bent; it is not a *bending* test. It is basic mechanical and textile engineering that tensile tests generally cannot be used to determine bending properties in and of themselves. Typically, a tensile test places a sample in tension by extending it to a given strain level and measuring the dependent variable, tension. In contrast, a typical bending test applies a bending moment to a specimen, measures the amount of deflection in response to the bending moment, and determines from this data a bending modulus or bending rigidity. A tensile test can be used to determine the bending modulus only in the unique circumstance when the material that makes up the specimen's tensile and compressive moduli are equal and the material is monolithic, such

as certain monofilaments. By using a tensile test to determine bending rigidity, CETR assumes that coated FiberWire's tensile and compressive moduli are equal and uncoated FiberWire's tensile and compressive moduli are equal. Neither CETR nor Dr. Mukherjee provided any basis for this assumption. Without testing to prove that this assumption is correct or an explanation as to why it can be assumed, the "pliability" tests conducted by CETR are flawed.

46. The second reason the CETR "pliability" test is flawed is because it incorrectly assumes that *multifilament* FiberWire is a *monofilament*. CETR used the test method advanced in the Rodeheaver paper (Mukherjee Res. Report at Ex. 13) to determine FiberWire's pliability. But the mathematical relationship used by Rodeheaver to determine pliability assumes that the tested suture is a *monofilament* (Mukherjee Res. Report at Ex. 13 at 528). By assuming a monofilament structure, CETR simplistically assumes that a multifilament suture's pliability can be determined by measuring the tensile modulus, measuring suture diameter, and determining the moment of inertia of the suture. But FiberWire is a *multifilament* suture. To determine the bending rigidity of a multifilament textile structure, such as a suture, using the Rodeheaver equation is erroneous. It is well known in the textile field that a multifilament structure's bending rigidity is proportional to the number of filaments, the modulus of elasticity, the fiber-to-fiber mobility and *the individual moment of inertia of each filament.*[4] In other words, the fiber-to-fiber mobility of the multifilament structure will affect the effective structural moment of inertia. Therefore, the Rodeheaver equation cannot be used to determine the pliability for FiberWire.

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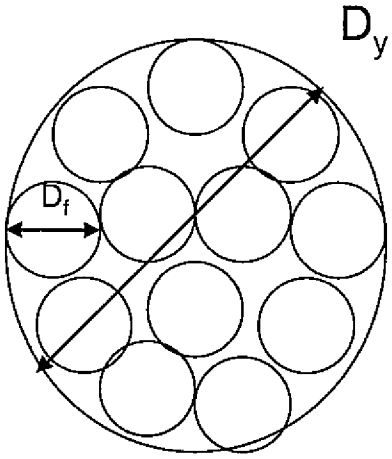
[4] *Mechanics of Elastic Performance of Textile Materials, Part XIV: Some Aspects of Bending Rigidity of Singles Yarns*, Platt, M., Klein, W. and Hamburger, W., Textile Research Journal, August 1959 pp. 611-627 (Ex. DD).

47. To understand the errors in Dr. Mukherjee's analysis, consider three example structures and how their bending strength or pliability can be determined. First, consider a monofilament of constant material (and assuming an equal compressive and tensile moduli) and cross-sectional circular shape ("monofilament"). The Rodeheaver test is applicable to such a monofilament structure. Second, consider a multifilament which has total freedom of inter-fiber movement during bending ("multifilament"). Such a multifilament's bending properties can be understood with reference to the 1959 seminal paper by Platt, Klein and Hamburger (Ex. DD). As Platt et al. describe, for a multifilament having complete freedom of fiber movement the product of the bending modulus (E) and the moment of inertia (I) of a yarn is proportional to $N_f E_f I_f$ where N_f refers to the number of individual fibers, E_f refers to the individual fiber modulus, and I_f refers to the moment of inertia of an individual fiber. Third, consider a multifilament that does not have total freedom of inter-fiber movement during bending. The monofilament and multifilament (having complete fiber mobility) can be considered two extreme conditions with the multifilament not having complete freedom of fiber movement being between the other two conditions. Because FiberWire's structure is a braided multifilament, there cannot be complete freedom of fiber movement.

48. To understand the error in Dr. Mukherjee's analysis, I will contrast a hypothetical monofilament structure with a hypothetical multifilament with complete freedom of inter-fiber movement with reference to the Figure below (each multifilament acts independent of its neighboring filament).



Assume $4*D_f = D_y$. For a monofilament type structure, the moment of inertia would be $\pi D_y^4/64$, which is the equation used by CETR and originally advanced by Rodeheaver. But for a multifilament having 12 fibers and total freedom of movement, as shown in the picture, the moment of inertia is $12*\pi D_f^4/64$. Accordingly, the monofilament's and multifilament's moment of inertia, and therefore their bending rigidity, are not equal. Because FiberWire is neither a monofilament nor a multifilament having complete independent fiber movement, its bending stiffness is somewhere between a monofilament and multifilament structure. Thus, assuming FiberWire is a monofilament, as Dr. Mukherjee and the CETR testing assume, also produces errors.

49. The third reason that I disagree that Dr. Mukherjee can draw conclusions from CETR's "pliability tests" is that CETR incorrectly assumes that the FiberWire samples have a circular cross section and that the diameter of each FiberWire suture is constant and equal to 0.65 mm. (Mukherjee Res. Report at Ex. 20 at 3). The Rodeheaver paper assumes a constant circular cross section. Dr. Mukherjee and CETR do not provide any basis for the assumption that the FiberWire samples have a constant circular cross section. The Rodeheaver paper also assumes a

constant diameter along the linear axis of the tested structure. Dr. Mukherjee and CETR do not provide any basis for the assumption that the tested FiberWire samples have a constant diameter along their linear axis. I have consulted with Dr. Matt Hermes. Based on his experience, he opined that even amongst the same USP size suture, suture diameters vary along their linear axis. I have reviewed the attached summary of Pearsalls' batch records, and they show variation in FiberWire's diameter for sutures made from same batch (Ex. AA). For example, the suture diameter varies between the "dye" (uncoated) and "intermediate" (coated) stages, as well as between the "intermediate" and "measure" stages. Thus, FiberWire varies in diameter, and it was incorrect for Dr. Mukherjee and CETR to assume that it does not. This error in assuming that the diameter is always the same is magnified to the fourth power because, in the monofilament equation used by Dr. Mukherjee, the diameter of the suture is raised to the fourth power (Ex. 20 of Mukherjee Res. Report at 3).

50. I also note that CETR's "pliability test" graph is not an accurate depiction of the tensile stress-strain relationship. CETR uses a non-linear, non-logarithmic scale on the horizontal axis. This distorts the true slope of the data. Also, I am not sure whether CETR reported all of its data in this graph or a portion of the data. I note that the data reported seems to be only part of a stress-strain curve that is obtained from a typical tension test. I know this because Figure 2 does not show the strain to failure of either of the samples.

51. I also disagree with the conclusions that Dr. Mukherjee draws from the "pliability" tests because they appear to be contradicted by his "knot slippage strength tests" and "knot run-down tests." I have consulted with Dr. Hermes and, from what we know about these tests, they are basically a type of tension test, similar to the "pliability" test conducted by CETR. Therefore, the slope of the curve from these tests before slippage or run down should be similar to that

obtained in CETR's "pliability" test. But they are not. During the pliability tests, CETR found that the coated suture had a lower modulus, as shown by its smaller slope (Mukherjee Res. Report at Ex. 20 at 3-4). In contrast, the other two CETR tests report a higher modulus for the coated suture, but it is not clear by how much from the graph and data (Mukherjee Res. Report at Ex. 20 at 5-8). The point being that the tests results are inconsistent. They appear to contradict the conclusions drawn by Dr. Mukherjee from the CETR "pliability" tests. Based on the limited information that I have about the tests, they are either inconclusive or show that coating has no material affect on tensile strength because the variations are due to the testing, not the material.

52. I also disagree with the conclusions that Dr. Mukherjee draws from the "pliability" tests because they appear to be contradicted by Pearsalls' testing. Ex. AA summarizes the results of Pearsalls' tension tests on batches of FiberWire at the "dye," "intermediate," and "measure" stages. Pearsalls found that FiberWire's tensile strength basically stayed the same between the uncoated FiberWire and FiberWire that underwent the coating processes. Although there are some variations in the reported measurements (*i.e.*, the tensile strength appears to go up, down, and stay the same), it is my opinion that these are really just an artifact of the testing (*i.e.*, operator variations, knot tying, or the expected variations inherent to textile testing) and not true variations (see paragraphs 40-41). I note that Dr. Mukherjee ignores these data in his analysis.

(4) Dr. Mukherjee's "Drape" Test Is Flawed & Inconclusive

53. I have considered Dr. Mukherjee's "drape test." This "test" is overly simplistic and flawed. Dr. Mukherjee states that he performed his drape test by "draping the suture over [his] extended index finger and observing the degree to which the suture conforms to the shape of [his] finger" (Mukherjee Res. Report at 27). First, I do not understand what he means by "conforms to the shape of my finger." Therefore, I cannot fully respond to his statement

because, among other reasons, I cannot tell what he measured. Second, it appears that Dr. Mukherjee is attempting to approximate FiberWire's pliability by determining FiberWire's ability to bend by using his finger as a test rig. But this method is flawed because he did not provide a true cantilever end support. Consequently, there is no defined position as to where FiberWire begins its bending, and no definitive way to determine the degree of bending. Third, diameter affects pliability, and Dr. Mukhejee does not provide any diameter measurements for the samples that he compared. Therefore, based on what I can determine from his report, it is not possible to scientifically compare the pliability of the uncoated and coated FiberWire using this method.

54. I note that Dr. Mukherjee relies on documents that refer to Ethicon and Mitek products in his analysis (Mukherjee Res. Report at 23-24, Mukherjee Res. Report Exs. 14, 15, 17, & 18). I disagree that these documents are relevant to the analysis because they discuss products and coatings that are different than FiberWire. It is my opinion, that the effect of FiberWire's coating on FiberWire cannot be determined with reference to other products.

B. If Dr. Mukherjee Is Correct Regarding The Meaning Of The Novel And Basic Characteristics, TigerWire's Nylon Does Not Materially Affect Them

55. Dr. Mukherjee has opined that TigerWire does not infringe for the same reasons that he expressed regarding FiberWire (Mukherjee Res. Report at 30). I disagree for the reasons stated above with respect to FiberWire.

56. I understand that the differences between TigerWire and FiberWire are that TigerWire is not dyed blue and replaces one PET yarn strand with one black nylon yarn strand. Dr. Mukherjee opines that TigerWire's nylon materially affects pliability (Mukherjee Res. Report at 30-31). I disagree. The purpose of the nylon strand is for visual identification (Ex. V at 74:21-23). It is my opinion that replacing one PET yarn with one nylon yarn does not materially affect

the novel and basic characteristics of the claimed suture because the nylon marker does not prevent or materially affect FiberWire's PET and UHMWPE from being dissimilar, from being braided, or from being braided to have improved handleability and pliability without significantly sacrificing physical properties. I note that Dr. Mukherjee does not opine otherwise. Rather, he seems to opine that the nylon marker affects pliability. He does not address the issue of whether FiberWire's braid of dissimilar yarns with improved handleability and pliability performance without significantly sacrificing physical properties is affected.

57. Dr. Mukherjee states that TigerWire's nylon yarn "make[s] TigerWire stiffer" than FiberWire, and "materially" affects "pliability" (Mukherjee Res. Report at 31). He also states that "nylon 6,6 fibers of the type used in TigerWire are generally more stiff (*i.e.* less pliable) than fibers made of PET, as used in FiberWire and TigerWire" (Mukherjee Res. Report at 30). I again disagree. First, I disagree that generally TigerWire's nylon 6,6 fibers are necessarily stiffer than PET fibers. Dr. Mukherjee cites to his Ex. 26 for the principle that nylon is stiffer than PET. But Ex. 26 shows the comparative characteristics of "unfilled" PET and "molding compound" nylon. These are not the characteristics of fibers made from these polymers. Thus, it is my opinion that it is improper, absent further information, to rely on this molding compound data for fiber properties. Even if it were proper to rely on this data, Ex. 26 shows that PET has a flexural modulus of 350,000 psi to 450,000 psi and that nylon 6,6 has a flexural modulus of 410,000 psi to 470,000 psi. There is a significant overlap in these ranges. Based on this data, it is possible that nylon 6,6 fibers and PET fibers used in FiberWire and TigerWire have substantially the same flexibility. In that instance, the substitution of one nylon fiber for one PET fiber would have no substantial affect on the pliability of the braid. Second, even if the nylon and PET yarns have different flexibility, but the flexibility were still in the range cited in

Ex. 26, it is my opinion that replacing one nylon yarn with one PET yarn would not materially affect the suture's pliability because the two types of material are close enough in flexural modulus as to be essentially indistinguishable in the FiberWire braid. In fact, the one nylon yarn only makes up about 12% of the suture by weight (Ex. EE at ARM 14744).

58. Dr. Murkherjee's opinion that nylon 66 is generally more stiff than polyester is contradicted by *Marks' Standard Handbook for Mechanical Engineers* (Ex. J at Table 2 at p. 6-155). The elastic modulus of nylon 66 fiber ranges from 25 to 50 gpd and the elastic modulus for polyester fiber, which I read to include polyester, ranges from 50-80 gpd. Thus, it is indicated that nylon 66 fiber is *less stiff* than polyester.

59. My opinion that TigerWire's nylon does not materially affect TigerWire's pliability is supported by Arthrex's testimony. My. Dreyfuss from Arthrex testified that TigerWire and FiberWire show "very similar" knot strength, tensile strength, [and] handleability (Ex. V at 76:1-5). Also, Mr. Dreyfuss testified that that the nylon strand had only "minute" effects on the feel of the suture as compared to FiberWire (Ex. V at 75:13).

60. I understand that Dr. Mukherjee relies on a "drape" test comparing FiberWire and TigerWire. My comments and opinions about Dr. Mukherjee's "drape" test above apply here as well. Additionally, I do not understand what Dr. Mukherjee means when his says "to a much greater degree" and the "course [sic] feel would suggest that the addition of the nylon would adversely affect knot tie-down" (Mukherjee Res. Report at 31). Therefore, I cannot really respond to his opinion. Nevertheless, I understand that Dr. Hermes has considered both no. 2 TigerWire and FiberWire. I also understand that he could not determine any significant difference in the stiffness of TigerWire and FiberWire. Again, Dr. Mukherjee provides no diameter measurements for the samples, and diameter can affect pliability.

C. If Dr. Mukherjee Is Correct Regarding The Meaning Of Novel And Basic Characteristics, The Adhesive As Used On Arthrex's FiberStick Product Does Not Materially Affect Them

61. Dr. Mukherjee has opined that FiberStick does not infringe for the same reasons that he expressed regarding FiberWire (Mukherjee Res. Report at 31-32). I disagree for the reasons stated above with respect to FiberWire. Dr. Mukherjee also states that FiberStick's adhesive materially affects "suture" handleability and therefore concludes that the adhesive materially affects the novel and basic characteristics, as he defines them. It is not my opinion that the adhesive materially affects the novel and basic characteristics, as they are defined by Dr. Mukherjee, because about 38 inches of FiberWire does not have adhesive. The adhesive is irrelevant to the portion of FiberStick's that has no adhesive. Because the portion of FiberStick that has no adhesive still infringes, there is no reason to even consider the adhesive.

62. Arthrex's intended use of FiberStick confirms my opinion that the portion of FiberStick that has adhesive is irrelevant to the properties of the portion that has no adhesive. As I understand FiberStick, it is about a 50 inch length of FiberWire that has about 12 inches of its length treated with Loc-Tite (Ex. FF at ARM1495 at 13-2 and Ex. V at 122:1-15). According to FiberStick's design history file, a portion of FiberStick is treated to "allow for suture loading" and for suture passing through cannulated instruments (Ex. GG at ARM7847). Further, according to Arthrex's intended use, once FiberStick has been passed through a cannulated instrument, the portion having adhesive "can then be cut leaving the remaining suture in place to perform repairs" (Ex. GG at ARM7848). In fact, after the Loc-Tite treated portion of FiberStick has been cut and disposed of, Arthrex promotes using FiberStick's untreated "suture" portion in the "fashion identical to that which is currently marketed" (Ex. GG at ARM7850). The remaining suture is simply a FiberWire suture. As Arthrex states, the treated end does not "affect the design" of the suture (Ex. GG at ARM7848) or "change the intended use or

indication" (Ex. GG at ARM7850). The adhesive portion is only for suture placement; it does not affect the remainder of the suture. Thus, Arthrex's intended use for FiberStick confirms my opinion that the adhesive has no material effect on the portion of FiberStick that does not have adhesive.

V. Reverse Doctrine of Equivalents

63. I have been asked to opine on the issue of whether the reverse doctrine of equivalents applies to FiberWire. Based on discussions with counsel, I understand that the reverse doctrine of equivalents applies when an accused product literally contains all the elements of a claim, but the product is so far changed in principle that it performs the function of the claimed invention in a substantially different way. It is my opinion that the reverse doctrine of equivalents does not apply because FiberWire is not so far changed in principle from the suture claimed in the 446 Patent. I disagree that FiberWire is so far changed in principle that it performs the function of the claimed invention in a substantially different way for the reasons explained above with reference to the doctrine of equivalents (*see* Section III).

VI. FiberWire's Success Is Not Due To Just FiberWire's UHMWPE

64. Dr. Mukherjee opines that he disagrees with my opinion that "some of the benefits marketed by Arthrex in selling FiberWire (and TigerWire) are due to the invention claimed in the '446 Patent" (Mukherjee Res. Report at 33). According to Dr. Mukherjee, the "superior aspects of FiberWire touted by Arthrex relate virtually exclusively to the increased strength from UHMWPE" (Mukherjee Res. Report at 34). I disagree with Dr. Mukherjee's statement. Dr. Mukherjee's statement is contradicted by Arthrex's own marketing documents, technical documents, and technical witnesses.

65. I also disagree with Dr. Mukherjee because he ignores all of the benefits advanced by Arthrex in Arthrex's marketing literature. For example, he ignores that Arthrex promotes that

FiberWire's "polyester braided jacket . . . gives FiberWire superior strength" and it promotes FiberWire as a "braided polyblend suture" (Mukherjee Res. Report at Ex. 30). He further ignores that Arthrex touts other properties such as "knot slippage," knot profile" to name a few, which can be attributed to the claimed heterogeneous braid (Mukherjee Res. Report at Ex. 30) for the reasons provided below.

66. Mr. Grafton, developer of Arthrex's FiberWire, testified that the increase in strength of FiberWire is not due to UHMWPE. Mr. Grafton testified that a 100% UHMWPE braided suture was unacceptable because the knot holding strength was too low (Ex. I at 46:7-15; 52:16-20). Mr. Grafton said that the knot holding strength was too low because of the lubricity of the UHMWPE. Mr. Grafton then had the idea of adding PET into the braided structure, so that the PET would increase the knot holding strength (Ex. I at 53:8-11; 54:9-14). It was not until Arthrex braided the UHMWPE with PET that the "polyblend" suture became acceptable (Ex. I at 54:9-55:15).

67. Mr. Grafton also represented to the Patent Office that UHMWPE alone was not acceptable in suture applications because the knot tie down or knot security was too low (Ex. I at 24:18-21; 103:25-104:12; Ex. R). Based on these statements from Mr. Grafton, I disagree with Dr. Mukherjee when he states that "superior aspects of FiberWire touted by Arthrex relate virtually exclusively to the increased strength from UHMWPE." Rather, FiberWire's benefits touted by Arthrex can be attributed at least in part to the invention claimed in the 446 Patent.

68. I reserve the right to comment further on Dr. Mukherjee's analyses and report when more information about the analyses becomes available. I may use trial demonstratives to explain my opinions.

Dated: April 13, 2006

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

CERTIFICATE OF SERVICE

I certify that the foregoing Rebuttal Expert Report of Dr. David Brookstein was served by Federal Express overnight mail on April 13, 2006 on the following:

Charles W. Saber
Dickstein, Shapiro, Morin & Oshinsky, LLP
2101 L. Street, NW
Washington, DC 20037-1526.

Christopher Weld, Jr.
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109

Dated: April 13, 2006

Erich M. Falke

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

March 23, 2006

Comparative Suture Testing

1. Introduction

Center for Tribology, Inc., abbreviated CETR, is a privately held California corporation, located in the heart of Silicon Valley in the city of Campbell, county of Santa Clara. It was founded by Dr. Norm Gitis in November 1993 and incorporated in California in October 1994. Its main charter has been helping major corporations and universities all over the world in research, development and failure analysis of materials, coatings and lubricants for the computer peripherals (20% of revenues), semiconductor (20% of revenues), biomedical (15% of revenues) and other industries (20% of revenues), as well as for fundamental academic studies (25% of revenues). A list of its customers is attached in Appendix 1.

CETR is a multi-million-dollars corporation with two lines of business, design & sales of mechanical & tribology test equipment (90% of revenues) and testing & consulting services on mechanical & tribological properties of materials and devices (10% of revenues).

CETR is one of the largest and leading producers of mechanical and tribology testers in the world. In particular, it has supplied them to leading domestic suture manufacturers, such as Ethicon, Inc. of Johnson & Johnson and United States Surgical of Tyco Healthcare, as well as such well-known corporations as Gillette, Guidant, Medtronic, Schick, Procter & Gamble, Unilever, etc.

Dr. Norm Gitis, President of CETR, is a well-known expert on tribology testing with 30 years of experience in friction, wear and fatigue testing of materials and devices. His resume is attached in Appendices 2a – 2c.

CETR has successfully provided highest quality laboratory test data in several lawsuits, including most recently between Alaska Airlines, Boeing, and families of victims of the Alaska flight 261 (related to the reliability of a jack-screw/nut assembly on Boeing airplanes and a plane crash in 2000), between American Airlines, Sabre Travel Network and Western Digital (related to the reliability of computer disk drives used for travel reservations), and between Boston Scientific and US Justice Department (related to the quality of implantable cardiovascular stents). It has been charging $ 2,500 per day or $ 10,000 per week for its regular lab testing services and double prices for priority urgent services.

Dr. Gitis has successfully testified in several depositions, most recently in a lawsuit between Seagate Technology and Cornice, Inc. related to the intellectual property on the mechanical design of portable magnetic disk drives. He has also given successful testimonies at several trials, most recently in lawsuits between Swiss Air, Interactive Flight Technology, Avnet and other parties (related to the reliability of computerized on-demand in-flight video system and a crash of Swiss flight 111) in the court of Arizona and between Iomega and Nomai (related to the reliability of Zip high-density floppy-drives) in the Higher Court of

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

United Kingdom, courts of Amsterdam, Dusseldorf, etc. He has been charging $ 350 per hour plus trip expenses for his consulting and expert witnessing services.

2. Project Goal

At the end of February 2006 CETR was requested by a law firm of Dickstein, Shapiro, Morin & Oshinsky, LLP (located at 2101 L Street NW, Washington, DC 20037) and its technical expert Dr. Debi Mukherjee to perform comparative mechanical and tribological testing of two types of FiberWire surgical sutures, coated and uncoated.

They requested the following parameters be tested: i) pliability/bendability, ii) knot tie-down/run-down, iii) knot security, iv) chatter, v) coefficient of friction, vi) tissue drag, vii) microscopy examination.

We have been told that this project is related to a patent infringement lawsuit between DePuy Mitek, a Johnson & Johnson company and Arthrex, the latter being the client of this law firm. Any details of the lawsuit have been neither requested by CETR nor provided to CETR.

3. Suture Samples

In the beginning of March 2006 CETR received via FedEx two new spools of US 2 FiberWire sutures from the law firm, one coated and the other uncoated. Each spool contained approximately 20 m of suture. Two CETR employees Dr. Norm Gitis and Mr. Michael Vinogradov examined the spools of sutures and found them to be apparently brand new.

Upon agreement with the law firm and Dr. Mukherjee, before conducting any tests, we sent both the spools of sutures for ETO sterilization to a reputable sterilization lab Sterile Systems, Division of Medtronic Inc. (located at 520 Watson S.W., Grand Rapids, MI 49504). The same Mr. Michael Vinogradov handled the sutures before the shipment and after receiving them back. Both shipments to and from Sterile Systems were performed via FedEx.

Upon receiving back the sterilized sutures, we handled them only and always with clean-room gloves. We cut about 3 m of each of the coated and uncoated sutures and shipped by FedEx to a surgeon expert, as requested by the law firm. The rest of the spools were utilized in our tests described below.

4. Set Of Test Procedures

Based on the CETR experience with its suture-tester customers Ethicon (New Jersey) and US Surgical (Connecticut), its general expertise in mechanical & tribology testing and familiarity with the relevant literature, as well as on the suggestions of the law firm, CETR has proposed a suit of test procedures for the requested tests, that was approved by the law firm's technical expert Dr. Mukherjee and then performed by CETR in mid-March, 2006.

5. Pliability Tests

The experimental procedure, based on the published work of Rodeheaver et al. [1], was as follows.

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Suture of 50 mm in length and 0.65 mm in diameter was clamped between the force sensor and the lower specimen holder as shown in fig. 1. The suture was preloaded with a tension of 0.5 Kg (5 N). Preloaded suture was then pulled at a force, uniformly increasing at the rate of 0.33 kg/sec. Force and elongation data were continuously monitored and recorded. The strain in the suture was calculated as the ratio of elongation to the initial length of 50 mm. The force-strain plots like the one shown in fig. 2 were made and their slopes were measured. Modulus of elasticity (E) was then calculated by dividing the slope with the cross-sectional area of the suture. Area moment of inertia (I) was calculated assuming a circular cross-sectional area. Stiffness was then calculated as a product of the modulus of elasticity and the area moment of inertia of the suture:

$$K = E*I$$

where
K – Stiffness,
E - Modulus of elasticity - Slope of the force-strain graph / cross-sectional area of the suture

I - Area moment of inertia - $\frac{\pi * D^4}{64}$ where D - diameter of the suture (0.65 mm)

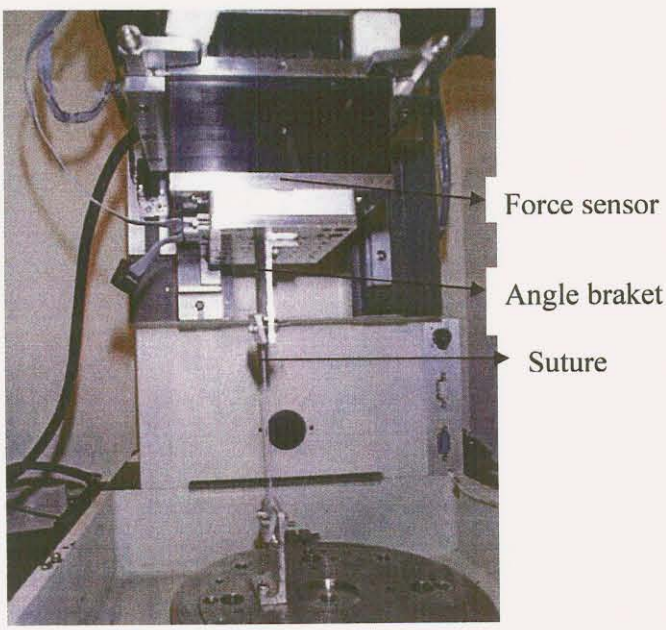

Figure 1. Test set up for pliability testing

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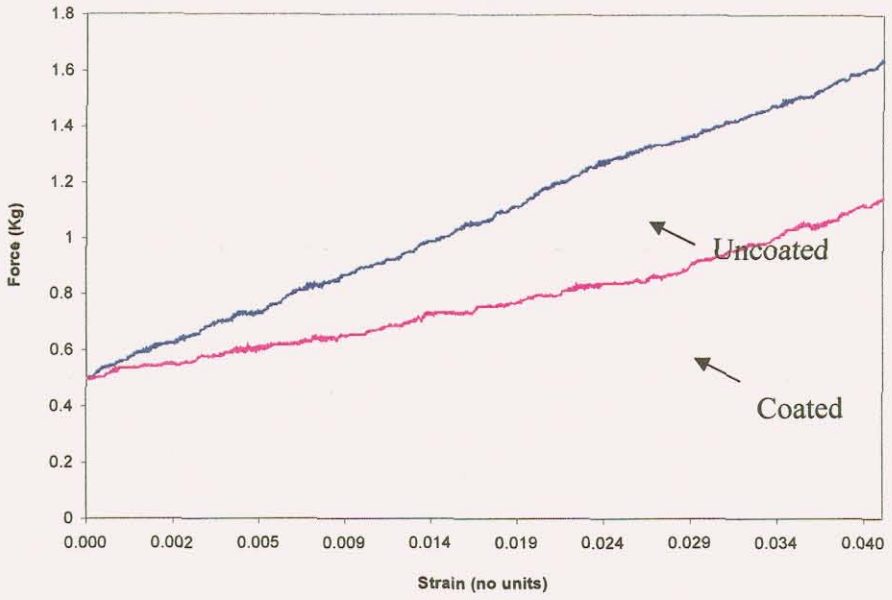

Figure 2. Typical force-strain data for coated and uncoated sutures during pliability tests

The stiffness values as calculated in the above described procedure are summarized in the Table 1.

Table 1. *Pliability test data*

Exp #	Stiffness (*E10-7 kg x m^2)	
	Coated Suture	Uncoated Suture
1	6.51	10.07
2	7.53	9.73
3	5.98	11.3
4	6.44	11.3
5	4.95	8.29
6	5.67	8.00
7	5.98	9.61
8	5.41	10.6
Average	6.06 ± 1.29	9.93 ± 1.66

The stiffness of the coated sutures was found to be lower than that of the uncoated ones. This suggests that the coated sutures have higher pliability and thus facilitate better handling during surgical use. The test data corresponds well to the data reported by Rodeheaver et al [1].

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6. Knot Slippage Strength Tests

The knot slippage strength tests were conducted to evaluate the knot security offered by each suture. The experimental procedure was carried out based on previous works in the literature [2, 3]. A loop of the suture was formed by tying a 'square knot' as shown in fig 3 [4] around a cylinder of 2.5 cm diameter. The loop thus formed was slipped off the cylinder and soaked in 0.9% weight/volume sodium chloride for 1 minute to closely represent the real environment. The soaked loop was then placed around 2 parallel brass rods of 5 mm diameter, which were mounted onto the UMT-2 machine as shown in fig. 4. A pre-load of 1 N was applied to the loop. The parallel rods were then pulled apart at a constant velocity of 1 mm/sec. The force was continuously monitored and recorded during the experiment. The force when the knot starts slipping was noted as the knot slippage force. The rods continued to be pulled apart until either the knot got untied or a slippage of 3 mm occurred. The force at that instant gives the knot failure force.

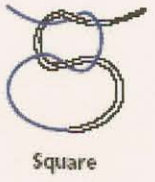

Figure. 3 'Square knot' used for the knot slippage strength tets

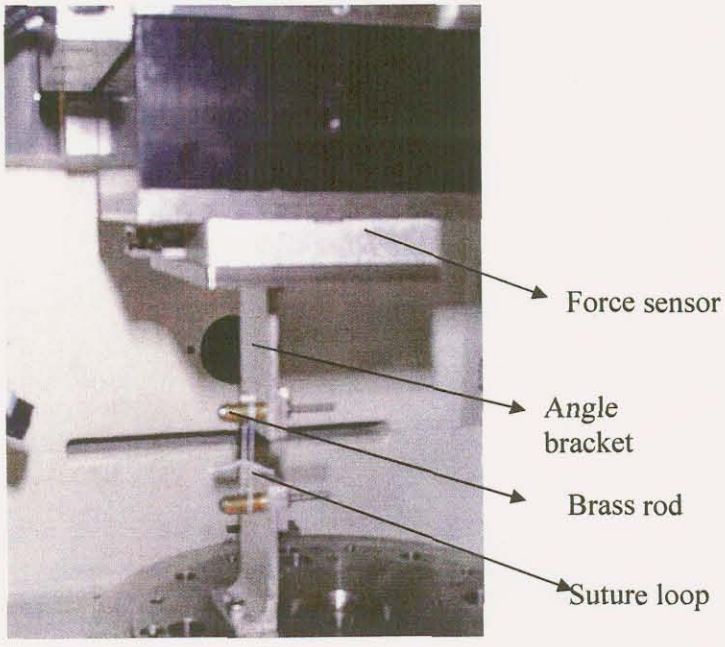

Figure 4. Test set up for knot slippage strength measurement

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The typical force response curves as recorded during the experiments are presented in the fig. 5 below.

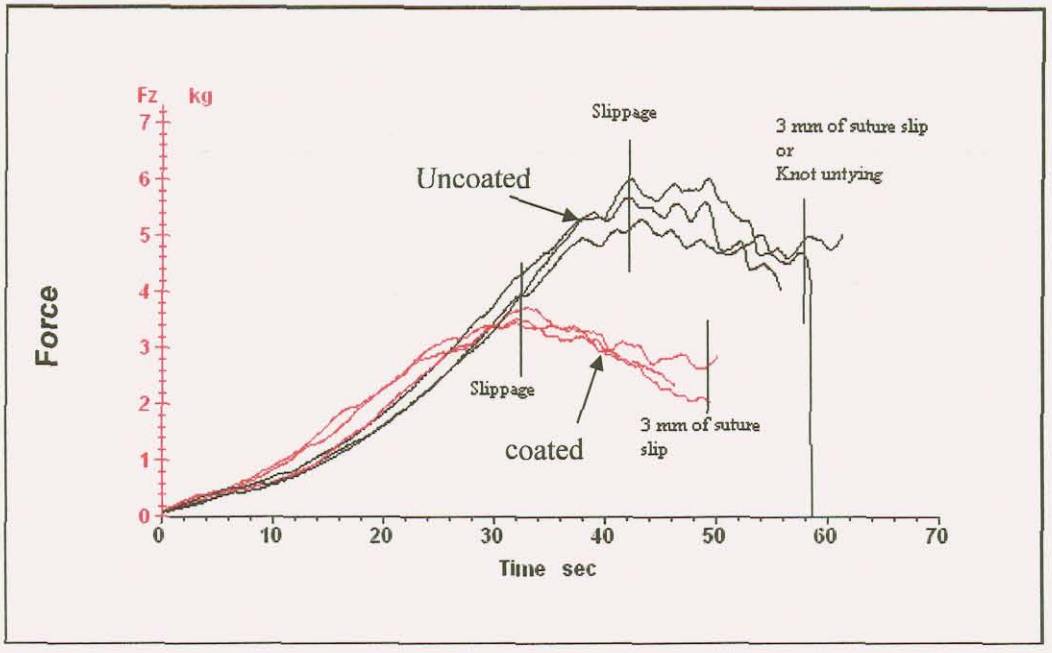

Figure 5. Typical data for force at slippage and knot failure for coated and uncoated sutures

The knot strength values as determined from the curves are summarized in the Table 2 below.

Table 2. Knot strength data for coated and uncoated sutures

Exp #	Knot strength (kg)			
	at slippage		at knot failure	
	Coated	Uncoated	Coated	Uncoated
1	3.52	5.33	3.06	4.09
2	2.36	4.97	2.03	4.09
3	3.46	4.80	3.15	2.42
4	4.25	6.04	2.07	2.98
5	3.74	4.70	2.40	3.53
6	2.43	5.36	2.77	4.79
7	3.47	4.86	2.09	3.45
8	3.27	5.10	2.64	3.90
Average	3.31± 0.95	5.14 ± 0.67	2.52 ± 0.56	3.36 ± 1.19

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From the above data it can be concluded that the knots tied using the coated sutures slipped and failed at lower forces when compared to the knots tied using uncoated sutures. The experimental data compare well with the data reported in the previous works [2, 3].

7. Knot Run-down Tests

The suture was tied with a 'half hitch knot' as shown in fig. 6 [4] around a supplemental cylinder with a 2.5 cm diameter. The loop thus formed was then slipped off the supplemental cylinder and placed on the lower brass rod of the UMT-2 testing machine. The knot was then subjected to running-down by pulling at a constant speed of 1.5 mm/sec on the longer free end in the testing machine as shown in fig. 7. The test procedure was based on the description provided in the literature [5]. The pulling force was continuously recorded as the knot traveled down the suture. Chatter or variation in knot run-down force was also noted.

Figure 6. Half-hitch tied for the knot run-down tests

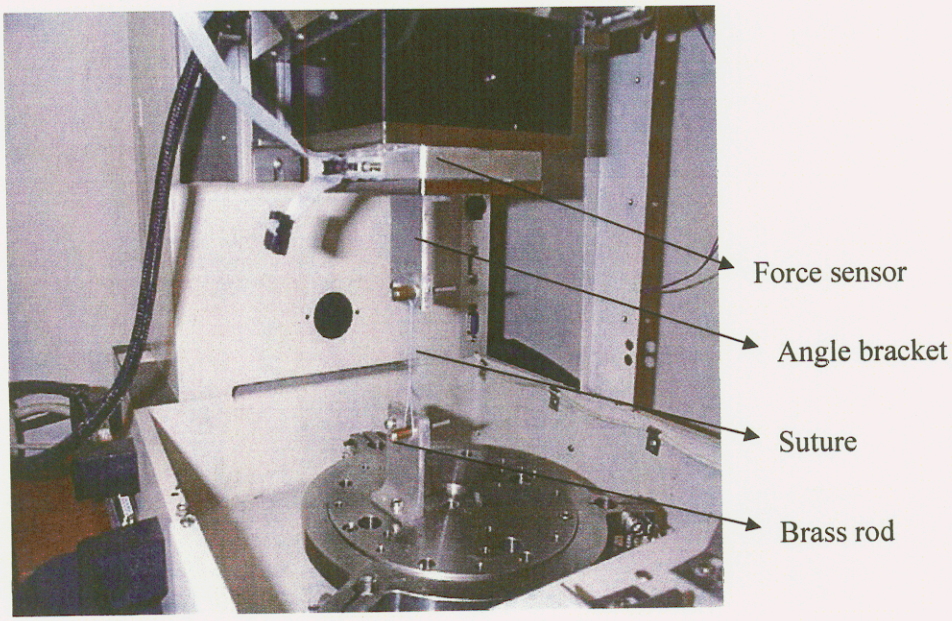

Figure 7. Test set up for the knot run-down test

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The typical pulling force data from the tests performed on coated and uncoated sutures plotted versus time is shown in fig. 8 below:

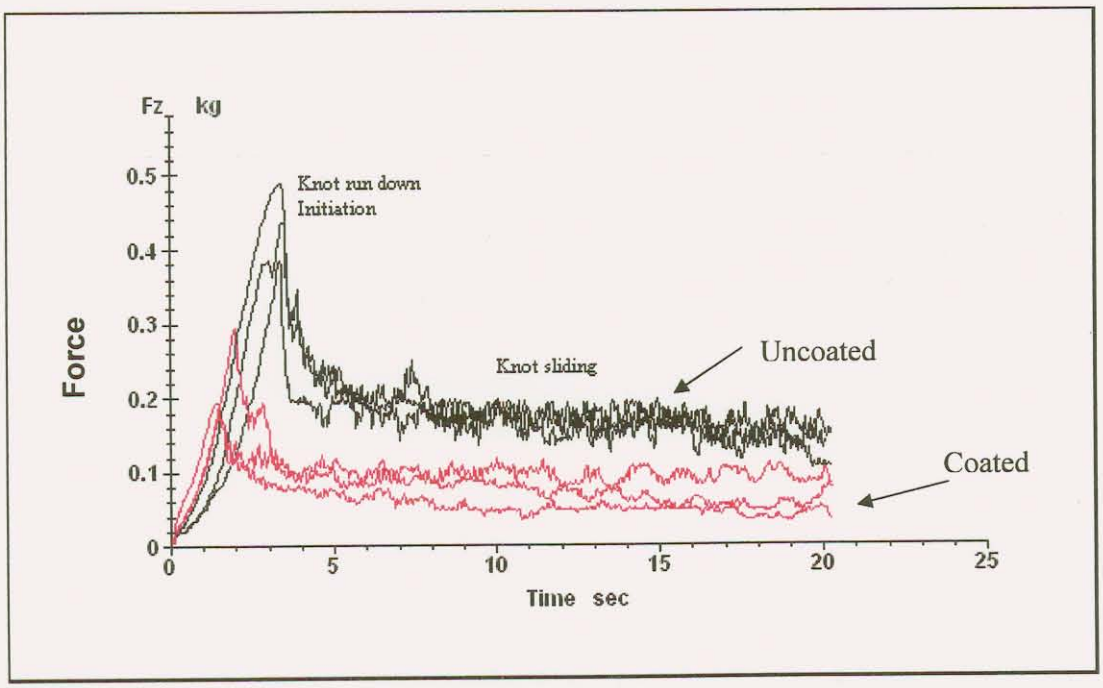

Figure 8. Force versus time for coated and uncoated sutures during knot run-down experiments

The force when the knot begins to slide over the suture was noted from the pulling force data. This gives the run-down force. The run-down force values as measured from the test data are tabulated in the Table. 3 below:

Table 3. Knot run-down test data

Exp #	Run-down force (kg)	
	Coated suture	Uncoated suture
1	0.28	0.39
2	0.20	0.54
3	0.26	0.42
4	0.22	0.49
6	0.18	0.44
7	0.19	0.28
8	0.21	0.26
average	0.22 ± 0.05	0.40 ± 0.14

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As can be seen from the above result, the coated sutures had lower run-down force when compared to the uncoated sutures.

8. Friction tests

The schematic of suture-on-suture testing set-up is shown in the fig. 9 below.

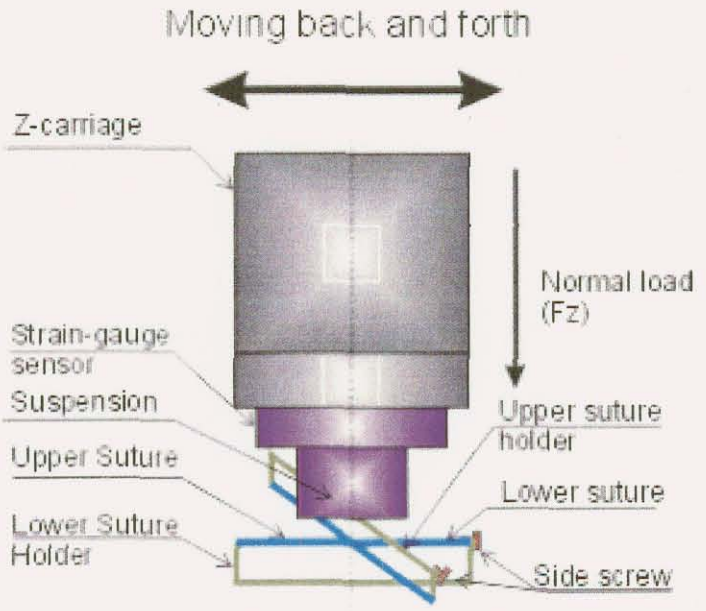

Figure 9. Test schematic for measuring suture-on-suture friction

A sample of suture was mounted and tensioned on the upper sample holder and another sample of the same suture was mounted and tensioned on the lower sample holder. The tension of both the sutures was adjusted using side screws to ensure constant tension for each suture, as shown in fig. 10. The upper suture was moved on the lower one back and forth with a reciprocating length of 3 mm at a frequency of 0.5 Hz under a constant normal load of 2 N (0.2 kg) for 200 seconds. A close-loop feedback loading mechanism ensured a constant normal force.

Both the applied vertical load and friction (shear) response force were continuously monitored and recorded during the tests.

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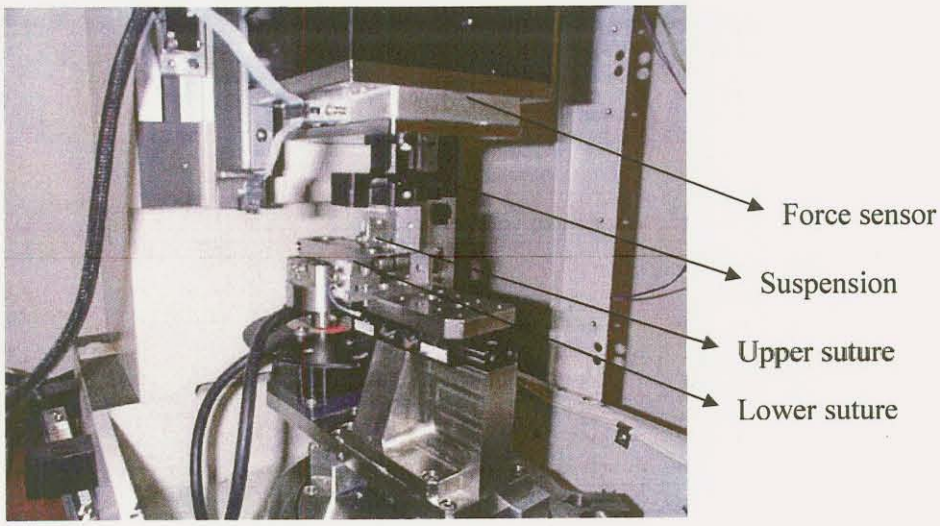

Figure 10. Set up of suture-on-suture friction tests

The coefficient of friction curves as recorded during the reciprocating tests are presented in fig. 11 below. The uncoated sutures had higher average coefficient of friction. The numerical data from the tests are noted and summarized in table. 4

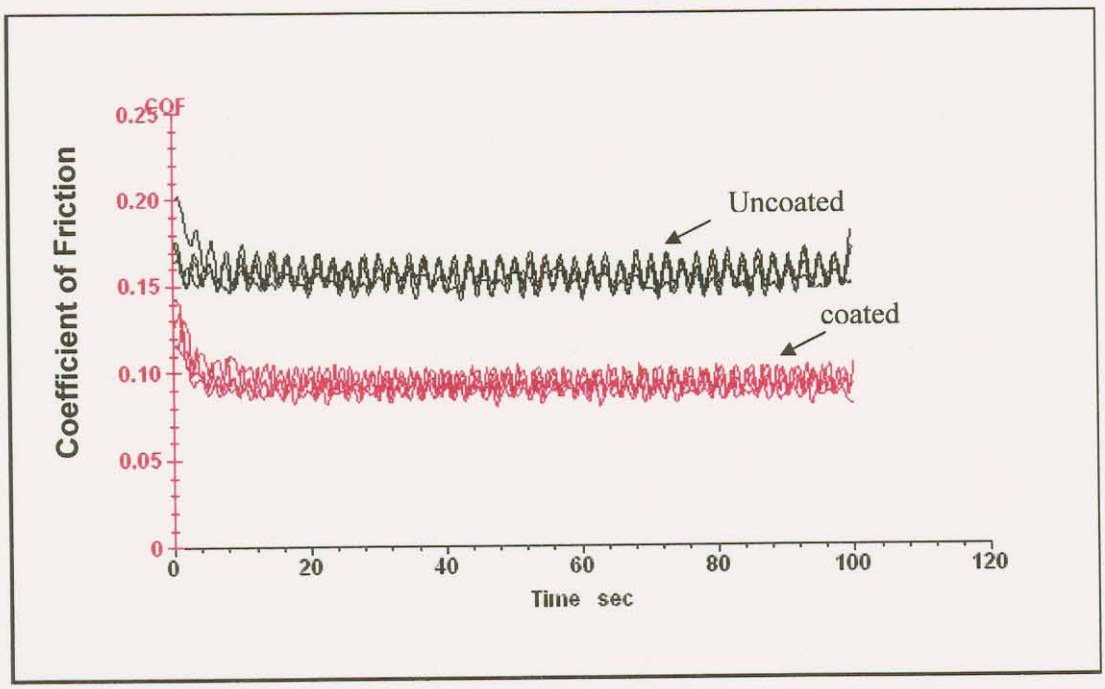

Figure 11. Typical Coefficient of Friction curves for Coated and Uncoated Sutures

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Table 4: Average coefficient of friction data from suture-on-suture tests

Exp #	Coefficient of Friction	
	Coated suture	Uncoated suture
1	0.09	0.15
2	0.10	0.17
3	0.08	0.16
4	0.10	0.16
5	0.09	0.16
6	0.09	0.16
7	0.09	0.17
8	0.10	0.17
Average	0.09 ± 0.01	0.16 ± 0.01

From the above results, it can be seen that the coated sutures have lower coefficient of friction when compared to the uncoated sutures. This result correlates well with the run-down force data in the previous section. The average coefficient of friction data is similar to the previous data [1, 6].

9. Chatter Data

Chatter is termed as the variation in friction during knot run-down and/or reciprocating friction tests. These variations are due to stick-slip process between the interacting suture surfaces when the knot is tied-down [5]. The difference between the maximum and the minimum friction coefficients, or amplitude of frictional auto-oscillations, is the measure of the chatter. Chatter data measured from both the knot run-down and the suture-on-suture friction tests are summarized in the table 5 below.

Table 5: Chatter data from knot run-down and suture-on-suture tests

Test #	Chatter data	
	Coated suture	Uncoated suture
1	0.009	0.013
2	0.009	0.017
3	0.008	0.013
4	0.008	0.013
5	0.010	0.012
6	0.012	0.011
7	0.008	0.014
8	0.010	0.019
average	0.009 ± 0.001	0.014 ± 0.003

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The chatter was higher for the uncoated sutures when compared to the coated ones. This result strengthens the conclusion from the previous results that coated sutures provide greater ease of handling during surgical use.

10. Tissue Drag Tests

The frictional force encountered during the passage of the suture through a tissue is termed as tissue drag. A 20-mm length of suture was pulled through a piece of leather at a constant rate of 1 mm/sec, while continuously recording the pulling force. The test procedure is based on the description provided in the previous works [7]. The leather piece was held in position using fixtures as shown in fig. 12. Two types of tests were performed: dragging the suture through the hole made with a needle and dragging the suture between two tightly clamped pieces of leather. In both cases, the upper end of the suture was attached to the UMT upper bracket providing the well-controlled motorized dragging action. The average drag force measured in both types of experiments was identical.

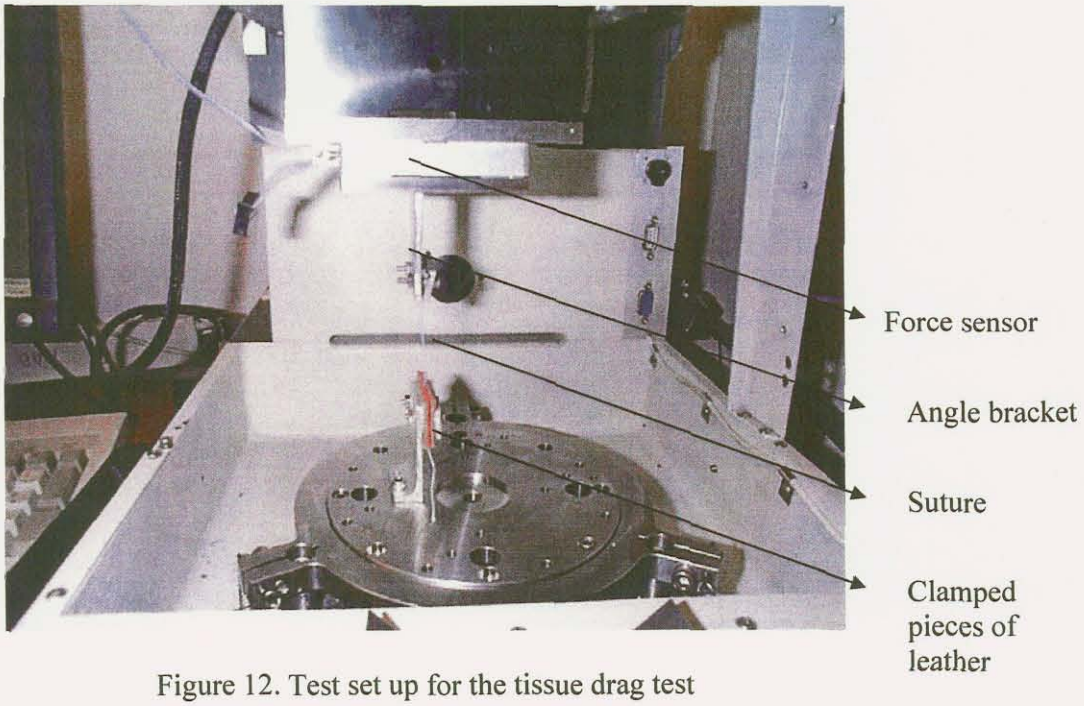

Figure 12. Test set up for the tissue drag test

Fig. 13 presents the force required to pull the coated and uncoated sutures. The highest force recorded gives a measure of the static drag force that was necessary to overcome in order to initiate the suture motion through the leather. The dynamic drag force was measured during the motion of the suture. The average static and dynamic drag forces are summarized in Table 6. The data are comparable to the previously reported results [1].

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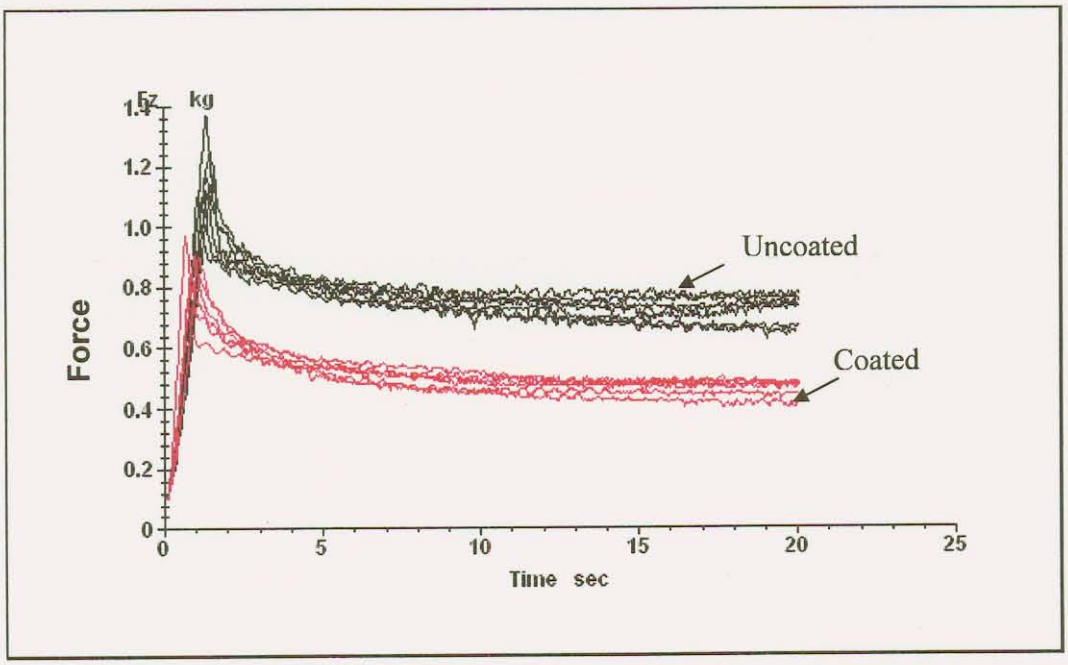

Figure 13. Typical force curves for coated and uncoated sutures.

Table 6. Drag force from the tissue drag tests

Exp #	Drag force (kg)			
	Static		Dynamic	
	Coated suture	Uncoated suture	Coated suture	Uncoated suture
1	1.10	1.15	0.55	0.74
2	0.85	1.20	0.52	0.78
3	0.71	1.19	0.41	0.84
4	0.68	1.39	0.46	0.91
5	0.97	1.10	0.46	0.85
6	1.11	1.19	0.58	0.64
7	0.90	1.13	0.51	0.77
8	0.92	1.13	0.50	0.72
Average	0.91 ± 0.20	1.18 ± 0.15	0.50 ± 0.11	0.78 ± 0.14

11. Microscopy Data

We have attempted to stud y the structure of the sutures with a digital optical microscope, attached to the same UMT tester, but the structure was undistinguishable. So, we utilized

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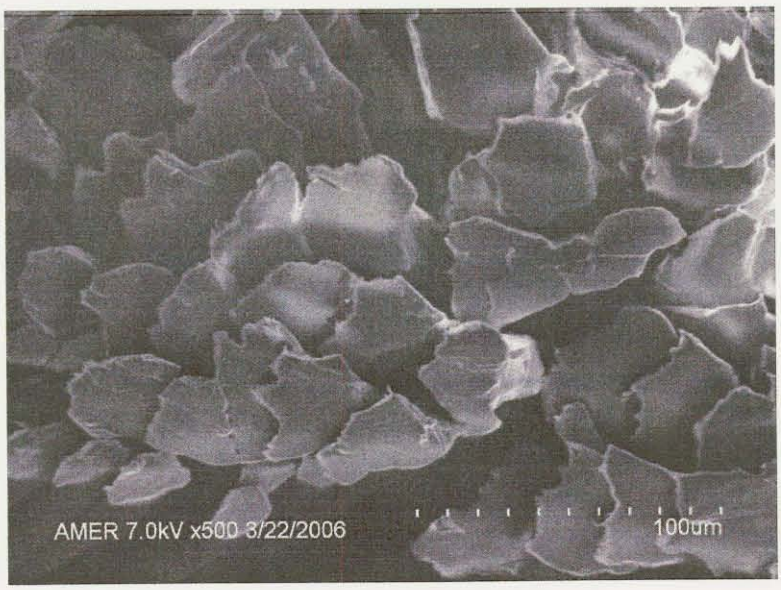
laboratory imaging services of a reputable local analytical lab AMER in Sunnyvale, California. Dr. Gitis brought samples of the uncoated and coated sutures to AMER and was present there all the time while their lab engineer Tony Lin performed SEM (scanning electron microscopy) imaging.

The obtained images are presented below in figures 14 and 15.



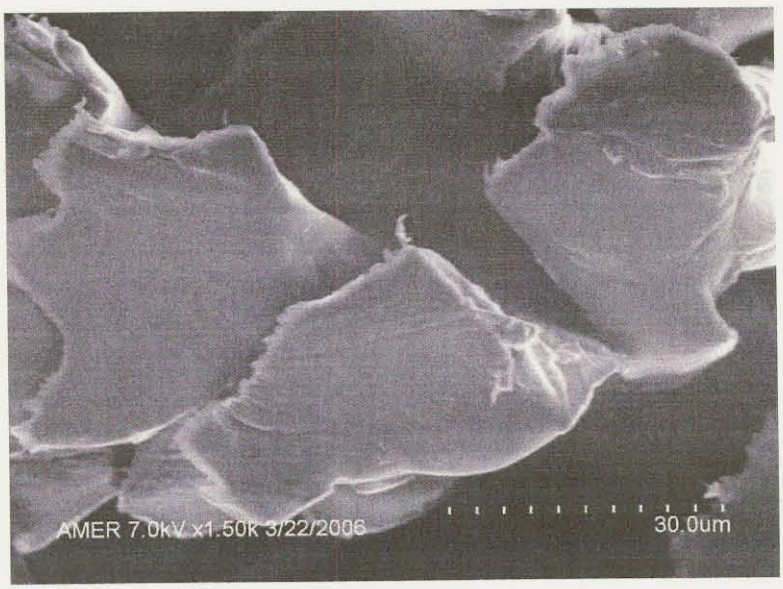


Figure 14. SEM Photos of the Coated Suture

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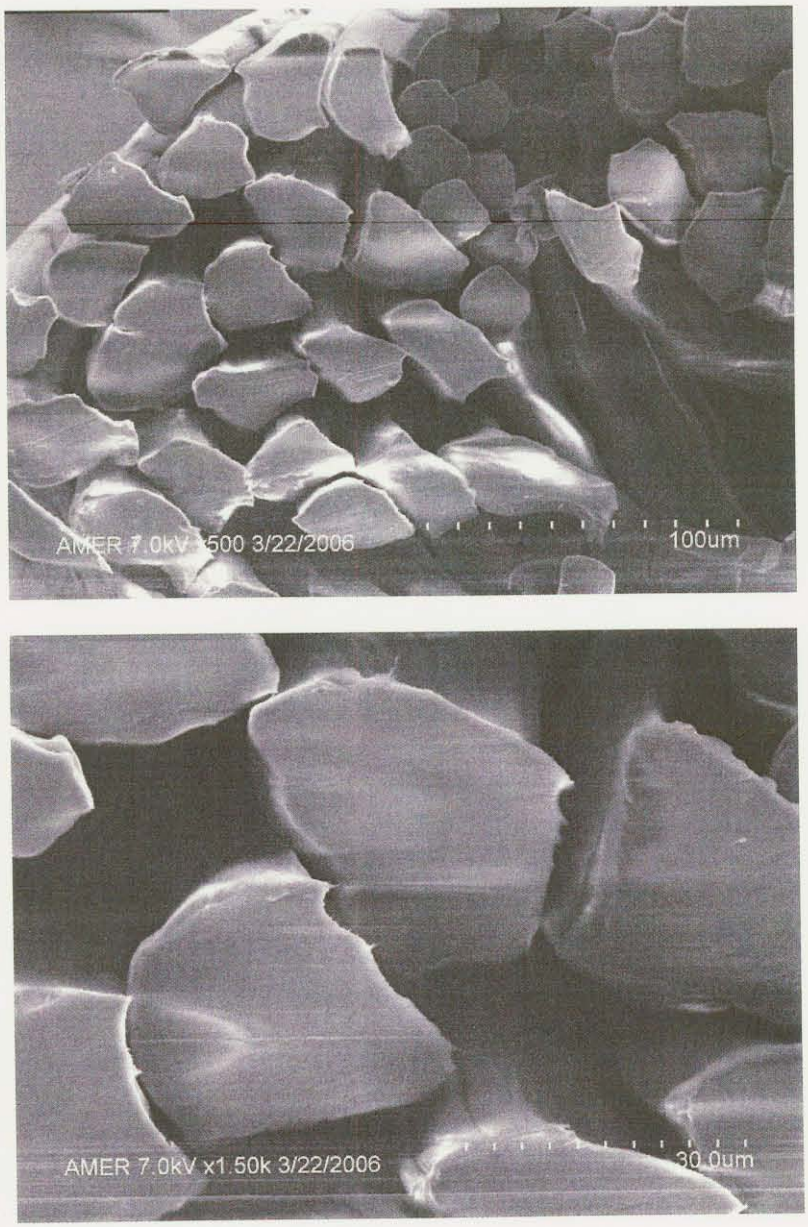

Figure 15. SEM Photos of Uncoated Sutures

12. Statistical Significance of Test Data

We used a common t-distribution statistical analysis, assuming the test data to be normally distributed The t-analysis assesses whether the means of two data groups are statistically

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different from each other. Then the test statistic (t-value) is calculated as [8, 9]:

$$t = \frac{X_u - X_c}{\sqrt{\frac{V_c}{N_c} + \frac{V_u}{N_u}}}$$

where X_c and V_c - mean and variance, correspondingly, of data for coated suture,
X_u and V_u - mean and variance, correspondingly, of data for uncoated suture,
N_c and N_u - number of tests for coated and uncoated sutures, correspondingly (N = 8).

The calculated t-values for all our test data are presented in Table 7 below.

Table 7. Comparison of t-values for data significance

Test	Coated		Uncoated		Experimental "t"-value	"T" threshold
	Xc	Vc	Xu	Vu	t	T
Stiffness	6.06 E-6	6.17 E -13	9.93 E-6	1.6 E -12	7.35	1.76
Slippage Strength	3.31	0.41	5.14	0.19	6.72	1.76
Untie Strength	2.52	0.2	3.66	0.54	3.72	1.76
Run-down Force	0.22	0.001	0.4	0.01	4.62	1.76
Friction	0.09	3.58 E -5	0.16	5.66 E -5	20.27	1.76
Chatter	0.009	1.58 E -6	0.014	6.91 E -6	4.63	1.76
Static drag	0.91	0.025	1.18	0.008	4.29	1.76
Dynamic drag	0.5	0.003	0.78	0.007	7.91	1.76

To make a conclusion that the difference between groups of data is statistically significant, the t-value should be larger when compared to a T-threshold calculated based on the degrees of freedom of the distribution and an error level. Degrees of freedom is calculated as [8]: DoF =

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Nc + Nu – 2 = 14. An error level of 0.05 (5%) is most commonly used. Based on the DoF and error level, the T-threshold is found from a standard t-distribution table [8, 9] to be T = 1.76.

As seen from the Table 7, the computed t-values of test data are much greater than the threshold T level, which allows us to conclude that the observed differences between coated and uncoated sutures are statistically significant.

Norm Gitis

Dr. Norm Gitis
President, Center for Tribology, Inc.
Chairman, STLE Technical Committee on Tribotesting

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Appendix 1. CETR Customers, 1993 – 2006

No.	Customer	State/Country
1	3M Corporation	Minnesota, Singapore
2	ABB Flexible Automation	Michigan
3	Abrasive Technology	Ohio
4	Advanced Elastomer Systems	Ohio
5	Advanced Refractory Technologies	New York
6	Advanced Surface Microscopy	Indiana
7	Advanced Urological	California
8	Akashic Memories	California
9	Alcatel	California
10	Alcoa	Pennsylvania
11	Alps	Japan
12	Alvyn	California
13	Ampex	California
14	Apple Computer	California
15	Applied Magnetics	California
16	Applied Material Technologies	California
17	Applied Materials	California
18	Applied MicroStructures	California
19	Ararat Industrial	Mexico
20	Asahi-Komag	Japan
21	ATMI	Texas
22	Atrua Technologies	California
23	Auto Wax	Texas
24	Bausch & Lomb	New York
25	Bell Microproducts	California
26	Borg Warner Automotive	New York
27	Cabot Microelectronics	Illinois
28	Carbone of America	Virginia
29	Cargill	Minnesota
30	Cartesian Data	California
31	Castlewood Systems	California
32	Castrol North America	Illinois, New Jersey
33	Censtor	California
34	Chevron	California
35	China Univ. of Mining Technology	China
36	City of San Francisco	California
37	Climax Research	Michigan
38	Colorado School of Mines	Colorado
39	Conner Peripherals	California
40	Conner Technology	Colorado
41	Corning	New York
42	Creare	New Hampshire
43	CTC Consultants	California
44	DaLian University of Technology	China
45	Dana Corporation	Ohio
46	DAS Devices	California
47	Dell Computer	Texas
48	Delphi Harrison	New York
49	Denso	Japan
50	Digital Papyrus	California
51	Dow Chemical	Michigan
52	Draper Laboratory	Massachusetts
53	Dresden Technical University	Germany
54	DuPont	Delaware, New Jersey
55	Dyneon	Minnesota
56	Eastman Kodak	New York
57	Ecolab	Minneapolis
58	EKC Technology	California
59	Elpida Memory	Japan
60	Embraco	Brazil
61	Essilor	France
62	Ethicon	New Jersey
63	ETH-Zurich	Switzerland
64	ExcelStor Technology	Colorado
65	Exponent	Florida, Massachusetts
66	ExxonMobil	New Jersey
67	Federal-Mogul	Michigan
68	First Automobile Works	China
69	Flex Foot	California
70	Ford Visteon	Michigan
71	FormFactor	California
72	Fuji Electric	Japan, Malaysia
73	Fujitsu	Japan
74	Function Engineering	California
75	General Electric	New York
76	General Motors	Michigan
77	Gillette	Massachusetts
78	GOJO Industries	Ohio
79	Greene, Tweed & Co	Pennsylvania
80	Guardian Industries	Michigan
81	Guidant	Minnesota
82	H.B. Fuller Co	Minnesota
83	Hares Group	Ukraine
84	Harris Corporation	Florida
85	Headway	California
86	Henan University	China
87	Henkel Surface Technologies	Michigan
88	Hewlett Packard	CA, ID, OR, WA, Singapore
89	Hitachi	Japan, California
90	Hitachi Metals	Japan
91	HMT Technology	California
92	Hoffmann & Co	Austria
93	Honeywell Aerospace	Arizona
94	Honeywell Automotive	Ohio
95	Howmet Casting	Michigan
96	Hoya	Japan, California
97	Hyper-Therm HTC	California
98	Hyundai Motor	South Korea
99	IBM	California, New York, China
100	ICI Chemicals	United Kingdom
101	Imation	Minnesota
102	Imperial Oil	Canada
103	Infineon Technologies	Germany
104	Infineum	United Kingdom
105	Intel	Oregon
106	Interactive Flight Technology	Arizona
107	Intermec	Washington
108	Iomega	Utah, California, Malaysia
109	JDS Uniphase	California
110	JiLin University	China
111	JSR Micro	California, Japan
112	JTS	California
113	Juniper Networks, Inc.	California
114	K2 Optronics	California
115	Kaifa	China
116	Kanagawa Industrial Research Institute	Japan
117	Katsina Optics	California
118	Kobe Steel	California, Japan
119	Komag	California, Malaysia
120	Konica	Japan
121	Korea Research Institute of Chemical Technology	South Korea
122	Korea Testing Laboratory	South Korea
123	Korean Institute of Science & Tech.	South Korea
124	Kubota	Japan
125	Kuwait University	Kuwait
126	Lam Research	California
127	Lanzhou Inst. Chemical Physics	China
128	Louisiana State University	Louisiana
129	Loyola Marymount University	California
130	Lucent Technologies	New Jersey, New York
131	Luleå University of Technology	Sweden

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132	Mahle Metal Leve	Brazil
133	Mannheim Univ. Applied Sciences	Germany
134	MarQlin	California
135	Marquez Glasseries	Maryland
136	MAT	Japan
137	Matsushita Electronics	Japan
138	Maxtor	California, Colorado
139	Medtronic	California
140	Michelin	Russia
141	Micropolis	California, Singapore
142	MicroStor	California
143	MIT	Massachusetts
144	Mitsubishi Chemical	Japan, California
145	Mitsumi Electronics	Japan
146	MMC Technology	California
147	MMR Technologies	California
148	Morganite	North Carolina
149	Moscow State University	Russia
150	MRCC	North Carolina
151	MTEC	Thailand
152	Nalco Chemical	Illinois
153	Nanjing University of Aeronautics	China
154	Nanyang Technological Univ.	Singapore
155	NASA	California, Maryland
156	National Inst. for Space Research	Brazil
157	National Institute of Advanced Industrial Science & Technology	Japan
158	National University of Singapore	Singapore
159	Near Inc.	California
160	NEC	Japan, California
161	Network Associates	California
162	New Focus	California
163	NHK	Japan
164	NICS Electronics	South Korea
165	Nippon Sheet Glass	Japan
166	NOK	Japan
167	North Carolina A&T State Univ.	North Carolina
168	Northeastern University	Massachusetts
169	Northwestern University	Illinois
170	Novellus	Oregon
171	Nye Lubricants	Massachusetts
172	Optobionics	California
173	Owens-Illinois	Ohio
174	Pennzoil-Quaker	Texas
175	PerkinElmer Optoelectronics	Canada
176	PhaseMetric	California
177	Philips Multimedia	California
178	Piper Plastics	Arizona
179	Plasma Technology Inc.	California
180	Praxair	Indiana
181	PRI Automation	California
182	Procter & Gamble	Ohio
183	Qualcomm	California
184	Quantum	California, Massachusetts
185	Quinta	California
186	RadiSys	Oregon
187	Rain Bird Sprinkler	California
188	Raychem	California
189	Read-Rite	California, Japan, Thailand
190	Reset	California
191	RioSpring	California
192	Ritek	Taiwan
193	Rohm & Haas	Delaware
194	Rolex	Switzerland
195	Royal Canadian Mint	Canada
196	SAE Magnetics	California, China
197	Saesol Diamond	Korea
198	Saint-Gobain Perform. Plastics	California
199	Samsung	California, South Korea
200	Schick & Wilkinson Sword	Connecticut
201	Science & Technology Park of Venice VEGA	Italy
202	Seagate Technology	CA, CO, MN, OK, Brittan, Ireland, Thailand, Singapore
203	Sematech International	Texas
204	Sensormatic Electronics	Florida
205	Sequent Computer	Oregon
206	Shanghai Inst. Technical Physics	China
207	Shanghai Institute Microsystems	China
208	Sharp	Japan
209	Shenyang Inst. Metal Research	China
210	Shinhan Diamond	South Korea
211	Showa Denko	Japan, Singapore
212	Siemens	California
213	Silicon Valley Export Witness Group	California
214	Singapore Institute Manufacturing Technology (SIMTech)	Singapore
215	Siros	California
216	SKW Associates	California
217	Sony	Japan
218	Southern Illinois University	Illinois
219	Southwest Jia-Tong University	China
220	Space Research Institute # 510	China
221	SpeedFam-IPEC	Arizona
222	St.Jude Medical	Minnesota
223	Stanford University	California
224	State University of New York	New York
225	StorCard	California
226	StorMedia	California
227	Sub-One Technology	California
228	Sulzer Metco	New York
229	SurMet	Massachusetts
230	Swales Aerospace	Maryland
231	Symphonix	California
232	SyQuest	California
233	TDK	Japan
234	Telectronics	Colorado
235	TeraStor	California
236	Torlys	Canada
237	Toshiba	Japan, California
238	Trace Storage	Taiwan, California
239	Turtle Wax	Illinois
240	Tyco Fire and Security	Florida
241	Ultramet	California
242	Unilever	New Jersey
243	United States Surgical	Connecticut
244	University of Alabama	Alabama
245	University of Alaska	Alaska
246	University of Alberta	Canada
247	University of Arizona	Arizona
248	University of California	California
249	University of Idaho	Idaho
250	University of Leoben	Austria
251	University of Modena	Italy
252	University of Nottingham	England
253	University of South Carolina	South Carolina
254	University of South Florida	Florida
255	University of Sydney	Australia
256	University of Ulster	United Kingdom
257	Varian	California
258	Verbatim	California
259	Veridicom	California
260	Vichem-GelPak	California
261	Victrex	United Kingdom
262	Vigobyte International	California
263	Western Digital	CA, Singapore, Thailand
264	Western Michigan University	Michigan
265	Yonsei University	South Korea

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Appendix 2a. CV of Dr. Norm V. Gitis

Education

Ph.D., Mechanical Engineering & Tribology	1983	USSR Academy of Sciences
M.S., Mechanical Engineering	1978	USSR Polytechnic University

Doctoral Dissertation

Surface Roughness Optimization for Boundary-Lubricated Friction Joints, Moscow, 1983.

Employment History

Center for Tribology, Inc., Campbell	2000-now	President & CEO
Center for Tribology, Inc., Mountain View	1994-2000	President & Founder
Maxtor, San Jose	1992-1993	Tribology Manager
IBM, San Jose	1989-1992	Advisory Engineer
USSR Center for Machine Tools and Robotics, Moscow	1984-1988	Senior Lead Scientist
Petrochemical University, Moscow	1986-1988	Adjunct Professor
Tribology Center of USSR Academy of Sciences, Moscow	1978-1983	Research Scientist

Professional Society/Committee Membership

Chairman, Technical Committee on Tribotesting, Society of Tribologists and Lubrication Engineers	1998 - 2005
Vice-Chair, G-02.40 Subcommittee on Wear, ASTM	2000 - 2004
Member, Research Committee on Tribology, American Society of Mechanical Engineers	1996 - 1998
Member, Tribology Division, American Society of Mechanical Engineers	1991 - 2000
Member, Society of Tribologists and Lubrication Engineers	1990 - 2005
Member, International Disk Drive Equipment and Materials Association	1993 - 2005

Technical Conferences/Symposia

Chairman and/or organizer of 23 international tribology and tribo-metrology meetings and symposia (see table attached) in the United States (Detroit, Hawaii, Houston, Las Vegas, Los Angeles, Nashville, New York, Orlando, Pittsburgh, San Jose), Austria (Vienna), Canada (Calgary, Toronto), Japan (Morioka, Yokohama, Kobe), Uzbekistan (Tashkent). Organizer of 28 technical sessions at 11 STLE annual meetings (1993-1994, 1998-2006).

Technical Presentations

Invited speaker at over 70 international conferences and symposia, 55 seminars at major universities and academic research centers, 170 major industrial research engineering centers of corporations in the USA, as well as Austria, China, Germany, Ireland, Japan, Korea, Netherlands, Russia, Singapore, Taiwan, Thailand (see table attached).

CEO of #1 Fastest Growing Private Company in Silicon Valley, 1997.
Guest Professor at JiLin University, China, 2002.
Honorary Member of Japanese Society of Tribologists, 1992.
Summa Cum Laude Graduation, Russia, 1978.

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Patents

USA Patents (Related to Tribotesting)

1. *Patent No 6,502,455* of Jan 7, 2003. Microscratch Test Method and Indenter, (with M. Vinogradov), filed Sept 25, 2000.
2. *Patent No 6,418,776* of Jul 16, 2002. Method and Apparatus for Measuring Friction and Wear, (with M. Vinogradov, et al), filed July 24, 2000.
3. *Patent No 6,363,798* of Apr 2, 2002. Method and Device for Measuring Forces, (with M. Vinogradov, et al), filed July 24, 2000.
4. *Patent No 6,324,918* of Dec 4, 2001. Bi-directional Force Sensor, (with M. Vinogradov, et al.), filed June 5, 2000.
5. *Patent No 5,795,990* of Aug 18, 1998. Method and Apparatus for Measuring Friction and Wear Characteristics of Materials, (with L. Levinson, et al.), filed July 30, 1997.

USA Patents (Related to Precision Polishing)

1. *Patent No 6,702,646* of March 9, 2004. Method and Apparatus for Monitoring Polishing Plate Condition, (with M. Vinogradov), filed July 1, 2002.
2. *Patent No 6,585,562* of July 1, 2003. Method and Apparatus for Polishing Control With Signal Peak Analysis, (with M. Vinogradov), filed Sept 17, 2001.
3. *Patent No 6,494,765* of Dec 17, 2002. Method and Apparatus for Polishing Control, (with M. Vinogradov), filed May 17, 2001.
4. *Patent No 6,257,953* of July 10, 2001. Method and Apparatus for Controlled Polishing, (with M. Vinogradov), filed Sept 25, 2000.

USA Patents (Related to Magnetic Disk Drives)

1. *Patent No 6,559,108* of May 6, 2003. Perfluoropolyether Compounds as Magnetic Media Lubricants, (with J. Howell, et al.), filed Nov 15, 2000.
2. *Patent No 5,455,727* of Oct.3, 1995. Transducer-Suspension Assembly, (with D. Baral, et al.), filed Aug.9, 1994.

USA Patents (Related to Particle Detection)

1. *Patent No 6,573,836* of June 3, 2003. Method and Apparatus for Detecting The Presence of Powdered Material, (with R. Mavliev, et al.), filed Jan 4, 2002.

USA Patents (Related to Surgical Instruments)

1. Patent Pending. Multi-portal Device and Method for Percutaneous Surgery, (with T. Alamin, et al), filed May 10, 2002.
2. Patent Pending. Multi-portal Device with Linked Cannulae and Method for Percutaneous Surgery, (with T. Alamin, et al), filed May 21, 2002.

USSR Patents (Related to Antifriction Coatings and Designs)

1. *Patent No 1,545,576*. Composition for an Antifrictional Composite Material, (with A. Lapidus, et al.). Priority 3/14/88, registered 10/22/89, unpublished as state secret.
2. *Patent No 1,490,924*. Epoxy Compound for Antifrictional Wear-Resistant Coatings, (with A. Lapidus, et al.). Priority 9/7/87, registered 3/1/89, unpublished as state secret.
3. *Patent No 1,436,654*. Magnetic Devise for Unloading of Frictional Joints, (with A. Lapidus, et al.). Priority 6/7/87, registered 8/4/88, unpublished as state secret.
4. *Patent No 1,413,830*. Method of Mechanical Treatment of Machine Tool Slideways, (with D. Levit and B. Fragin). Published Bull. 28, 1988.
5. *Patent No 1,368,519*. Sliding Bearing, (with A.Lapidus). Published Bull. 3, 1988.

USSR Patents (Related to Tribotesting)

1. *Patent No 1,448,887*. Method for Testing Antifrictional Properties of Lubricants. Priority 12/2/86, registered 9/1/88, unpublished as state secret.

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2. *Patent No 1,377,668*. Test Method for Friction-Induced Vibrations, (with A. Lapidus). Published Bull. 8, 1988.
3. *Patent No 1,352,317*. Method for Monitoring Friction Process, (with G. Saruchev, et al.). Published Bull. 42, 1987.
4. *Patent No 1,307,310*. Method for Monitoring Degree of Seizure, (with B. Chizhov and A. Lapidus). Published Bull. 16, 1987.
5. *Patent No 1,043,566*. Method of Lubricant Testing, (with I. Kragelskii). Published Bull. 35, 1983.
6. *Patent No 1,029,043*. Method and Device for Lubricant Testing, (with N. Alekseev, et al.). Published Bull. 26, 1983.

List of Publications

Friction Fundamentals and Stick-Slip

1. Nature of Friction Coefficient: Panel Discussion. *Lubrication Engineering*, 4, 1995, (with C.DellaCorte)
2. Mechanism of Frictional Auto-Oscillations. *Proceed. 6th Internat. Congress on Tribology Eurotrib'93*, Budapest, Vol. 3, 1993, 428 - 433.
3. Nature of Stick-Slip Effect. *Tribology and Mechanics of Magnetic Storage Systems*, Vol. 7, STLE SP-29, 1990, pp. 107 - 113.
4. Discussion on Stick-Slip and Velocity Dependence of Friction at Low Speeds. *Transact. ASME: Journ. of Tribology*, Vol. 113, 1991.
5. Effect of Slideway Materials on Positioning Accuracy of Moving Units in Machine Tools. *Soviet Engineer. Research*, Vol. 9, No 4, 1989, (with B.Chizhov).
6. Self-Induced Vibrations in the Transversing Units on Machine Tool Slideways. *Soviet Engineer. Research*, Vol. 8, No 4, 1988, (with B.Chizhov and A.Lapidus).
7. Study of Characteristics of Mixed Friction in Sliding Guideways. *Soviet Journ. of Friction and Wear*, Vol. 9, No 4, 1988, (with A.Lapidus and B.Chizhov)
8. *FRICTIONAL AUTO-OSCILLATIONS*, (in Russian), Moscow, Science Press, 1987, (with I.Kragelskii).
9. Investigation into the Characteristics of Mixed Friction in Slideways. *Soviet Engineer. Research*, Vol. 7, No 11, 1987, (with B.Chizhov and A.Lapidus)
10. Effect of Contact Pressure on the Stick-Slip Properties of Sliding Guideways. *Soviet Engineer. Research*, Vol. 7, No 1, 1987, (with B. Chizhov).
11. *METHODS OF FRICTION AND STICK-SLIP REDUCTION IN MACHINE TOOLS*, (in Russian), Moscow, Engineering Press, 1986.
12. Study of Anti-Stick-Slip Properties of Machine Tool Guideway Materials. *Soviet Journ. of Friction and Wear*, Vol. 7, No 5, 1986.

Metrology of Thin Films and Coatings

1. In-Situ Quantitative Integrated Nano+Micro Metrology. *Proceed. Intern. Tribology Conf., Kobe, Japan, June 2005,* (with A. Daugela and J. Xiao), p. D13.
2. Integrated Nano-SPM for Nano-Tribology. *Proceed. Intern. Conf. on Micro and Nano-Technology, Vienna, Austria, March 2005,* (with A. Daugela and J. Xiao), p. 385 - 389.
3. Quantitative Nano & Micro Metrology of Thin Films and Coatings. *Proceed. Intern. Conf. on Industrial Tribology, Mumbai, India, December 2004,* (with A. Daugela, A. Sikder and J. Xiao), p. D5.
4. In-Situ Quantitative Integrated Tribo-SPM Nano-Micro Metrology. *Proceed. ASME/STLE Intern. Tribology Conf., Long Beach, October 2004,* (with A. Daugela, A. Sikder and M. Vinogradov).

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5. Tribometrology of Thin Films and Coatings. *Proceed. 1st Intern. Conf. on Advanced Tribology,*
6. Singapore, December 2004 (with J. Xiao and M. Vinogradov), p. B59.
7. Multi-Sensor Durability Characterization of Thin Diamond-Like Films. *Proceed. ADC/FCI Conf.*, Tsukuba, Japan, August 2003 (with J. Xiao and M. Vinogradov).
8. Multi-Sensor Testing of Thin and Thick Coatings for Adhesion and Delamination. *Proceed. 26th Annual Meeting of Adhesion Society*, Myrtle Beach, February 2003 (with J. Xiao and M. Vinogradov).
9. Tribotesting – Latest Advancements and State of the Art. *Proceed. 3rd Intern. Conf. on Surface Engineering*, Southwest Jiatong Univ., Chengdu, China, October 2002, (with J. Xiao).

Surface Roughness and Waviness

1. Roughness Optimization of Slideways. *Soviet Engineer. Research*, Vol. 5, No 11, 1985, (with A. Lapidus).
2. Influence of the Machining Marks Direction on Friction in Boundary Lubrication. *Soviet Engineer. Research*, Vol. 5, No 3, 1985, (with I. Kragelskii).
3. Use of Acoustic Emission Method to Optimize Friction Surface Microrelief. *Soviet Journ. of Friction and Wear*, Vol. 5, No 5, 1984, (with I. Kragelskii, et al.).
4. *Optimization of Surface Micro-geometry at Boundary Friction.* (In Russian), Ph.D. Thesis. Moscow, Institute of Machine Sciences of the USSR Academy of Sciences, 1983.
5. Investigation and Optimization of Surface Microgeometry. *Quality Control and Properties of Machine Parts*, (in Russian), Kiev, Vol. 3, 1980.
6. Determination of Curvature Radii on the Actual Surfaces of Spur Gears. *Russian Engineer. Journ.*, Vol. 60, No 7, 1980, (with L. Shemper).
7. Changes in Microgeometry of Gear Teeth During Running-in. *Machine Parts*, (in Russian), Vol. 21, 1978, (with J. Kotov and S. Filipovich).

Lubrication and Lubricants

1. Investigation of Processes in Thin Lubricant Films and Their Effects on Friction. *Proceed. 8th Confer. on Colloidal Chemistry and Physico-Chemical Mechanics*, (in Russian), Tashkent, 1983, (with I.Kragelskii).
2. Calculations of the Activation Energy for a Film Starvation Effect. *Tribotechnics for Engineering*, (in Russian), Moscow, 1983, (with I.Bujanovskii and A.Ginzburg).
3. Investigation of the Film Starvation and its Prevention. *Tribotechnics for Engineering*, (in Russian), Moscow, 1983.
4. Evaluation of Film Starvation Tendency of Greases. *Soviet Journ. of Friction and Wear*, Vol. 4, No 1, 1983, (with I. Kragelskii).
5. Evaluation of Anti-Frictional Properties of Lubricants, (in Russian). *Theoretical and Applied Problems of Wear-Resistance in Engineering*, Leningrad, 1982.
6. Evaluation of Antifrictional Properties of Thin Lubricant Films. *Soviet Physics Articles / USSR Academy of Sciences*, Vol. 27, No 8, 1982, (with I. Kragelskii).
7. An Experimental Study of the Film Starvation Effect. *Soviet Journ. of Friction and Wear*, Vol. 3, No 3, 1982, (with I. Kragelskii, et al.)
8. Analytical Model of Film Starvation Conditions for Adsorptive and Chemisorptive Mechanisms of Film Recovery. *Problems of Friction and Wear*, (in Russian), Vol. 21, 1982, (with V.Kelle and I.Kragelskii).

Antifrictional Materials and Design of Sliding Bearings

1. Evaluation of Tribological Properties of Bimetals. *Proceed. Intern. Tribology Conf.*, Kobe, Japan, June 2005, (with M. Vinogradov), p. G15.

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2. Precision Experimental Measurements of Viscoelastic Properties of Industrial Polymers. *Proceed. 4th Intern Conf. Mechanics of Time-Dependent Materials,* Lake Placid, New York, October 2003.
3. Magnetic Unloading of Sliding Bearings and Guideways. *News of Machinebuilding*, (in Russian), No 2, 1991, (with A.Lapidus, et al.).
4. Advances in Tribology: Slideway Design and Unloading Systems. *Emerging Technology in the Soviet Union*, Delphic Ass., Washington, 1990.
5. How Epilamine Coating Affects the Stick-Slip Properties of Slideways. *Soviet Engineer. Research*, Vol. 8, No 9, 1988, (with A.Lapidus and B.Chizhov).
6. *PLASTIC AND COMPOSITE MATERIALS FOR SLIDING GUIDEWAYS*, (in Russian), Moscow, Engineering Press, 1987.
7. Comprehensive Tribological Tests for Slideway Materials. *Tribotechnics for Engineering*, (in Russian), Moscow, 1987.
8. Assessing the Anti-Stick-Slip Properties of Slideway Materials. Soviet Engineering Research, Vol. 6, No 3, 1986.
9. Antifrictional Polymers and Composites for Machine Tool Slideways. Wear in Machines and Methods of Its Reduction, (in Russian), Brjansk, 1985, (with A.Lapidus, et al.).
10. Increasing the Wear-Resistance of Slideways. Soviet Engineer. Research, Vol. 4, No 10, 1984, (with I.Kragelskii).

Seizure and Scuffing

1. Investigation of Non-Thermal Seizure in Machines. *Metalcutting Machine Tools*, (in Russian), Vol. 11, Kiev, 1983.
2. Effect of Mechanical Characteristics of Metals on the External Friction Threshold. *Problems of Friction and Wear*, (in Russian), Vol. 22, 1982.
3. Role of Microgeometry in Non-Thermal Seizure Development at Boundary Friction. *Mechanical Sciences - Machinovedeniye*, No 1, 1982.
4. Reliability of Machine Assemblies and External Friction Threshold. *Reliability in Machines*, (in Russian), Kuibyshev, 1981.
5. Evaluation of Non-Thermal Seizure in Spur Gears. *Proceed. Internat. Confer. JUGOMA-80*, (in Serbo-Croatian), Split, 1980, (with I.Kragelskii).
6. Study of Geometric Conditions of the External Friction Threshold for Cylindrical Gearing. *Soviet Journ. of Friction and Wear*, Vol. 1, No 6, 1980, (with I.Kragelskii).

Wafer Polishing and Planarization

1. Effects of Slurry Flow Rate and Pad Conditioning Temperature on Dishing, Erosion and Metal Loss During Copper CMP. *Proceed. AVS CMP User Group Symposium, San Jose, October 2005*, (with S. Kuiry, R. Mudhivarthi, M. Vinogradov and A. Kumar).
2. Effect if Slurry Flow Rate on Dishing, Erosion and Metal Loss During Copper CMP Process. *Proceed. VMIC Conference, Fremont, October 2005*, (with R. Mudhivarthi, S. Kuiry, M. Vinogradov and A. Kumar), pp. 367-372.
3. CMP Process and Consumables Evaluation with PadProbe. *Proceed. CMP-MIC Conference, Fremont, February 2005*, (with S. Hosali, E. Busch, M. Vinogradov).
4. CMP Consumables Characterization. *Proceed. CMP-MIC Conference, Fremont, February 2005*, (with S. Kuiry and M. Vinogradov).
5. In-situ Tribological Properties Monitoring and Chemical-Mechanical Characterization of Planarization Process. *Proceed. ASME/STLE Intern. Tribology Conf., Long Beach, October 2004,* (with A. Sikder, A. Daugela and M. Vinogradov).
6. CMP Process and Consumables Evaluation with PadProbe. *Proceed. AVS Intern. Conf. on Microelectronics and Interfaces,* Santa Clara, March 2004, (with J. Fang, K. Davis, etc.).

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7. Advanced Specification and Tests of CMP Retaining Rings. *Proceed. CMP-MIC Conference,* Los Angeles, February 2004, (with J. Xiao, A. Kumar and A. Sikder).
8. CMP Process and Consumables Evaluation with PadProbe. *Proceed. VLSI Multilevel Interconnection 20th Annual Conference,* Los Angeles, September 2003, (with J. Fang, K. Davis, etc.)
9. Incoming Inspection of CMP Consumables at the Semiconductor Fab. *Proceed. VLSI Multilevel Interconnection 20th Annual Conference,* Los Angeles, September 2003, (with M. Vinogradov).
10. Tribology Issues in CMP. *Semiconductor Fabtech*, Vol. 18, April 2003.
11. Delamination Studies in Cu/Ultra-Low-K Stack. *Proceed. CMP-MIC Conference*, Marina Del Rey, February 2003, (with A.Sikder, P. Zantye, etc.).
12. CMP In-Situ Pad Condition Monitoring with PadProbe. *Proceed. CMP-MIC Conference*, Marina Del Rey, February 2003, (with B.Kalenian, B.Pautsch, etc.).
13. PadProbe for Quantitative Control of Pad Condition and Wear. *Proceed. VLSI Multilevel Interconnection 19th Annual Conference,* Singapore, November 2002 (with M. Vinogradov, J. Xiao, A. Meyman).
14. Tribology Case Studies for Copper Removal Optimization. *Proceed. CMP Annual Symposium*, San Jose, October 2002 (with D. Craven, J. Jin).
15. PadProbe for Monitoring and Control of Pad Surfaces. *Proceed. CMP Annual Symposium*, San Jose, October 2002.
16. Quantitative Evaluation of CMP Process and Materials Using a CMP Tester. *Proceed. 2nd Intern. Conf. on Microelectronics and Interfaces*, Santa Clara, February 2001 (with M. Vinogradov).
17. Quantitative Evaluation of a CMP Process Using a Bench-top CMP Tester. *Proceed. 6th Intern. CMP-MIC Conf. on Chemical-Mechanical Planarization*, March 2001, (with M. Vinogradov).
18. Quantitative Functional Testing of CMP Materials Using a Bench-top CMP Tester. *Proceed. 18th Intern. VMIC Conf. on Multilevel Interconnection*, Santa Clara, September 2001 (with M. Vinogradov).

Tribology of Magnetic Disk Drives

1. Metrology for Micro-Tribology. *Proceed. MIPE'97*, Tokyo, July 1997, pp. 431-434.
2. Tribology of Near-contact Magnetic Recording. *Proceed. IDEMA Tribology Symposium*, Santa Clara, May 1996, pp. 117 - 130.
3. Challenges of and Ways to Achieve In-contact and Near-contact Recording. *Proceed. IDEMA Head/Media Interface Synposium*, San Jose, September 1994, pp. 47 - 58.
4. Phenomenon of Stiction in a Magnetic Head-Disk Interface. *Proceed. ASME Energy-Sources Conf.*, PD-Vol.61, New Orleans, January 1994, pp.11- 15.
5. Tribology of a Magnetic Head-Disk Interface with a Smooth Disk. *Proceed. MIT Tribology Symposium*, Cambridge, July 1993.
6. Study of Low Flying Height Using Acoustic Emission and Friction Techniques. *Advances in Information Storage Systems*, Vol. 6, 1995, pp. 107 - 120, (with C.Gerber).
7. Stiction Phenomenon in the Magnetic Disk-Slider Interface. *Proceed. 6th Intern. Congress on Tribology Eurotrib'93*, Budapest, Vol. 3, 1993, pp. 417 - 422.
8. Experimental Study of Stationary Head-Disk Contact in Magnetic Disk Drives. *Transact. ASME: Journ. of Tribology*, Vol. 115, 1993, pp. 214 - 218 (with R.Sonnenfeld).
9. Nature of Static Friction Time-Dependence. *Journ. Physics D: Applied Physics*, Vol. 25, 1992, pp. 605 - 612, (with L.Volpe).

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Appendix 2b. Technical Meetings Organized by Dr. Norm Gitis

Dr. Norm V. Gitis Chaired and/or Organized Technical Meetings						
No	**Topic of Meeting**	**Chaired / Organized**	**Conference/Symposium**	**Location**	**Month**	**Year**
1	Bio-Tribology	Chaired 1 session	Internl. Tribology Conference	Kobe, Japan	June	2005
2	Tribotesting	Organized 3 sessions, chaired 1 session	STLE Annual Meeting	Las Vegas, NV, USA	May	2005
3	Polishing Tribo-Metrology	Organized and chaired meeting	ASTM Working Group Meeting on CMP	Fremont, CA, USA	February	2005
4	Polishing Tribo-Metrology	Organized and chaired 1 session	CMP-MIC Conference	Fremont, CA, USA	February	2005
5	Tribotesting	Chaired 1 session	Internl Conf. on Surface Engineering	Shenzhen, China	October	2004
6	Tribotesting	Organized 4 sessions, chaired 2 sessions	STLE Annual Meeting	Toronto, Canada	May	2004
7	Polishing Tribo-Metrology	Organized and chaired 1 session	CMP-MIC Conference	Los Angeles, CA, USA	February	2004
8	Polishing Tribo-Metrology	Organized and chaired 1 session	VMIC Conference	Los Angeles, CA, USA	September	2003
9	Tribotesting	Organized 3 sessions and chaired 2 sessions	STLE Annual Meeting	New York, NY, USA	May	2003
10	Tribotesting	Organized 3 sessions and chaired 1 session	STLE Annual Meeting	Houston, TX, USA	May	2002
11	Tribotesting	Chaired 1 session	World Tribology Congress	Vienna, Austria	September	2001
12	Tribotesting	Organized 3 sessions and chaired 1 session	STLE Annual Meeting	Orlando, FL, USA	May	2001
13	Tribotesting	Organized 3 sessions and chaired 1 session	STLE Annual Meeting	Nashville, TN, USA	May	2000
14	Tribotesting	Organized 2 sessions and chaired 1 session	STLE Annual Meeting	Las Vegas, NV, USA	May	1999
15	Tribotesting	Organized 2 sessions and chaired 1 session	STLE Annual Meeting	Detroit, MI, USA	May	1998
16	Tribology of Head-Disk Interface	Organized symposium	IDEMA Tribology Symposium	San Jose, CA, USA	May	1996
17	Tribotesting and Micro-Tribology	Chaired 2 sessions	International Tribology Conference	Yokohama, Japan	October	1995
18	Tribology of Head-Disk Interface	Organized and chaired Plenar Discussion	ASME/STLE Tribology Conference	Hawaii, USA	October	1994
19	Tribology of Head-Disk Interface	Organized and chaired 1 session	Diskcon	San Jose, CA, USA	September	1994
20	Nature of Friction	Organized and chaired Plenar Discussion	STLE Annual Meeting	Pittsburgh, PA, USA	May	1994
21	Nature of Friction	Organized and chaired Plenar Discussion	STLE Annual Meeting	Calgary, Canada	May	1993
22	Micro-Tribology	Chaired 2 sessions	1st International Conf. On Micro-Tribology	Morioka, Japan	October	1992
23	Frictional Oscillations	Organized and chaired 1 session	International Tribology Conference	Tashkent, Uzbekistan	June	1985

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Appendix 2c. Dr. Norm Gitis' Presentations

No	Topic of Presentation	Conference/Company	Location	Month	Year
Conferences and Symposia					
1	Multi-Sensing Micro/Nano-Metrology	Taiwan Conference on Tribology & Materials Technology	Tainan, Taiwan	September	2005
2	Multi-Sensing Micro/Nano-Metrology	International Surface Engineering Congress	St. Paul, MN	August	2005
3	Tribo-Metrology for Bioengineering	International Tribology Conference	Kobe, Japan	June	2005
4	Tribo-Metrology of Lubricants	STLE Annual Meeting	Las Vegas, NV	May	2005
5	Multi-Sensing Micro/Nano-Metrology	STLE Annual Meeting	Las Vegas, NV	May	2005
6	Multi-Sensing Micro/Nano-Metrology	ICMCTF	San Diego, CA	May	2005
7	Tribo-Metrology for CMP Materials Control	MRS Spring Meeting	San Francisco, CA	April	2005
8	Multi-Sensing Micro/Nano-Metrology	International Conference on Nano-technology	Vienna, Austria	March	2005
9	Tribo-Metrology for CMP Process Control	CMP-MIC Conference	Fremont, CA	February	2005
10	Multi-Sensing Tribo-Micro/Nano-Metrology	International Conference on Industiral Tribology	Mumbai, India	December	2004
11	Multi-Sensing Micro/Nano-Metrology	MRS Fall Meeting	Boston, MA	December	2004
12	Multi-Sensing Micro/Nano-Metrology	AVS Annual Meeting	Anaheim, CA	November	2004
13	Tribo-Metrology of Skin	International Tribology Symposium	Xi'an, China	November	2004
14	Multi-Sensing Micro/Nano-Metrology	ASTM Symposium on Adhesion	Washington, DC	October	2004
15	Multi-Sensing Micro/Nano-Metrology	Japan Vacuum Society Conference	Tokyo, Japan	September	2004
16	Tribo-Metrology for CMP Materials Control	CMP Symposium	Lake Placid, NY	August	2004
17	Tribo-Metrology for Bioengineering	Society Experimental Mechanics Annual Congress	Costa Mesa, CA	June	2004
18	Tribo-Metrology for MEMS	Society Experimental Mechanics Annual Congress	Costa Mesa, CA	June	2004
19	Multi-Sensing Tribo-Micro/Nano-Metrology	STLE Annual Meeting	Toronto, Canada	May	2004
20	Multi-Sensing Tribo-Metrology of Coatings	Society of Vacuum Coaters Conference	Dallas, TX	April	2004
21	Tribo-Metrology for CMP Process Control	American Vacuum Society ICMI Conference	Santa Clara, CA	March	2004
22	Tribo-Metrology for CMP Process Control	CMP-MIC Conference	Los Angeles, CA	February	2004
23	Multi-Sensing Tribo-Metrology of Coatings	Adhesion Society Annual Meeting	Wilmington, NC	February	2004
24	Tribo-Metrology for MEMS CMP Process Control	Photonics West - Micromachining and Microfabrication	San Jose, CA	January	2004
25	Tribo-Metrology of Skin	ASME/STLE Tribology Conference	Point Vedra, FL	October	2003
26	Multi-Sensing Tribo-Metrology of Thin Films	IDEMA HDD Symposium	Tokyo, Japan	October	2003
27	Multi-Sensing Metrology of Polymers	Mechanics of Time-Dependent Materials	Lake Placid, NY	October	2003
28	Tribo-Metrology for CMP Materials Control	CMP-VMIC Conference	Los Angeles, CA	September	2003
29	Multi-Sensing Tribo-Metrology of Coatings	STLE Annual Meeting	New York, NY	May	2003
30	Multi-Sensing Tribo-Metrology of Advanced Materials	Adhesion Society Annual Meeting	Myrtle Beach, SC	February	2003
31	Multi-Sensing Tribo-Metrology of Advanced Materials	ASM International Santa Clara Valley Chapter	Sunnyvale, CA	January	2003
32	Tribo-Metrology for CMP Process Control	AVS CMP User Group Meeting	Sunnyvale, CA	September	2002
33	Multi-Sensing Tribo-Metrology of Advanced Materials	6th Chinese Tribology Conference	Lanzhou, China	August	2002
34	Multi-Sensing Tribo-Metrology of Advanced Materials	STLE Annual Meeting	Houston, TX	May	2002
35	Separation of Powders from Mail	1st Bioterrorism Mobilization Conf.	Seattle, WA	April	2002
36	Multi-Sensing Tribo-Micro/Nano-Metrology	SPIE Internat. Sympos. On Micromachining	San Francisco, CA	October	2001
37	Multi-Sensing Tribo-Metrology of Advanced Materials	World Tribology Congress	Vienna, Austria	September	2001
38	Multi-Sensing Tribo-Metrology of Coatings	STLE Annual Meeting	Orlando, FL	May	2001
39	Tribo-Metrology for Copper CMP Process Control	Internat. Sematech CMP Working Group Meeting	San Francisco, CA	April	2001

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40	Durability Evaluation of Ultra-Thin Coatings	Diskcon	Tokyo, Japan	April	2001
41	Tribological Bench-Top Evaluation of CMP Process	CMP-MIC Conference	Santa Clara, CA	March	2001
42	Quantitative Bench-Top Evaluation of CMP Process	AVS CMP User Group Meeting	Santa Clara, CA	December	2000
43	Durability Evaluation of Ultra-Thin Coatings	IDEMA Tribology Symposium	Tokyo, Japan	July	2000
44	Durability Evaluation of Ultra-Thin Coatings	IDEMA HDD Tribology Symposium	Longmont, CO	June	2000
45	Multi-Sensing Tribo-Metrology of Coatings	STLE Annual Meeting	Nashville, TN	May	2000
46	Tribo-Metrology of Thin Films and Coatings	STLE Annual Meeting	Las Vegas, NV	May	1999
47	Tribo-Metrology of Thin Films and Coatings	STLE Northern California Section	Oakland, CA	January	1999
48	Metrology for Micro-Tribology	STLE Annual Meeting	Detroit, MI	May	1998
49	Tribo-Metrology for MEMS	NSF/ASME Workshop: Tribology Issues in MEMS	Columbus, OH	November	1997
50	Multi-Sensing Tribo-Metrology of Coatings	World Tribology Congress	London, England	September	1997
51	Metrology for Micro-Tribology	MIPE	Tokyo, Japan	July	1997
52	Multi-Sensing Tribo-Metrology of Lubricants	STLE Annual Meeting	Kansas City	May	1997
53	Tribology of Near-Contact Head-Disk Interface	Diskcon	Tokyo, Japan	April	1997
54	Metrology for Micro-Tribology	IDEMA Tribology Symposium	San Jose, CA	May	1996
55	Micro-Tribology of Magnetic Head-Disk Interface	International Tribology Conference	Yokohama, Japan	October	1995
56	Tribology of Near-Contact Head-Disk Interface	6th Intern. Conf. on Magnetic Recording Media	Oxford, England	July	1995
57	Metrology for Micro-Tribology	STLE Northern California Section	Oakland, CA	March	1995
58	Tribology of Near-Contact Head-Disk Interface	Golden Gate Materials Conference	San Francisco, CA	February	1995
59	Tribology of Near-Contact Head-Disk Interface	ASME Energy Conference	New Orleans, LA	November	1994
60	Tribology of Near-Contact Head-Disk Interface	ASME/STLE Tribology Conference	Honolulu, HW	October	1994
61	Tribology of Near-Contact Head-Disk Interface	National Storage Information Consortium Meeting	Honolulu, HW	October	1994
62	Tribology of Near-Contact Head-Disk Interface	Diskcon	San Jose, CA	September	1994
63	Nature of Friction and Frictional Auto-Oscillations	STLE Annual Meeting	Pittsburgh, PA	May	1994
64	Nature of Friction and Frictional Auto-Oscillations	World Tribology Congress	Budapest, Hungary	August	1993
65	Micro-Tribology of Magnetic Head-Disk Interface	MIT Tribology Symposium	Cambridge, MA	July	1993
66	Micro-Tribology of Magnetic Head-Disk Interface	National Storage Information Consortium Meeting	San Jose, CA	May	1993
67	Nature of Friction and Frictional Auto-Oscillations	STLE Annual Meeting	Calgary, Canada	May	1993
68	Micro-Tribology of Magnetic Head-Disk Interface	ASME Winter Annual Meeting	Anaheim, CA	November	1992
69	Micro-Tribology of Magnetic Head-Disk Interface	1st International Workshop on Microtribology	Morioka, Japan	October	1992
70	Nature of Friction and Frictional Auto-Oscillations	ASME/STLE Tribology Conference	Toronto, Canada	October	1990
71	Optimization of Boundary Lubrication Regime	International Tribology Conference	Tashkent, Uzbekistan	May	1985
72	Tribo-Metrology of Lubricants	Wear in Machines Tribology Conference	Bryansk, Russia	May	1985
73	Tribo-Metrology of Lubricants	Wear Problems in Engineering	Leningrad, Russia	September	1982
74	Evaluation of Durability of Spur Gears	Wear in Machines Tribology Conference	Bryansk, Russia	May	1977

Universities and Academic Centers

1	Latest Achievements in Tribo-Metrology	Indian Institute of Technology	Mumbai, India	January	2006
2	Latest Achievements in Tribo-Metrology	University of Genova	Genova, Italy	June	2005
3	Latest Achievements in Tribo-Metrology	University of Hannover	Hannover, Germany	March	2005
4	Tribo-Metrology of Thin Films and Nano-Coatings	BAM	Berlin, Germany	March	2005
5	Tribo-Metrology of Thin Films and Nano-Coatings	University of Modena	Modena, Italy	March	2005
6	Latest Achievements in Tribo-Metrology	BEM Engineering College	Bangalore, India	December	2004
7	Latest Achievements in Tribo-Metrology	India Institute of Technology	Delhi, India	December	2004
8	Latest Achievements in Tribo-Metrology	Hong Kong Polytechnic University	Hong Kong, China	October	2004
9	Latest Achievements in Tribo-Metrology	City University of Hong Kong	Hong Kong, China	October	2004
10	Latest Achievements in Tribo-Metrology	University of Wisconsin	Milwaukee, WI	August	2004
11	Tribo-Metrology of Thin Films and Nano-Coatings	University of Illinois	Chicago, IL	August	2004

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12	Latest Achievements in Tribo-Metrology	Argonne National Laboratory	Argonne, IL	July	2004
13	Latest Achievements in Tribo-Metrology	Shanghai Jiao Tong University	Shanghai, China	March	2004
14	Tribo-Metrology of Thin Films and Nano-Coatings	North Carolina State University	Raleigh, NC	February	2004
15	Tribo-Metrology of Thin Films and Nano-Coatings	North Carolina A&T State University	Greenboro, NC	February	2004
16	Tribo-Metrology of CMP Process and Materials	International Microelectronics Consortium	Leuven, Belgium	February	2004
17	Tribo-Metrology of CMP Process and Materials	Shanghai Institute of Microsystem and Info Technology	Shanghai, China	December	2003
18	Tribo-Metrology of Thin Films and Nano-Coatings	Shanghai University	Shanghai, China	December	2003
19	Tribo-Metrology of CMP Process and Materials	Hebei Semiconductor Research Institute	Shijiazhuang, China	December	2003
20	Tribo-Metrology of CMP Process and Materials	Dalian University of Technology	Dalian, China	December	2003
21	Latest Achievements in Tribo-Metrology	Wuhan Research Institute of Materials Protection	Wuhan, China	December	2003
22	Tribo-Metrology of Thin Films and Nano-Coatings	University of Central Florida	Olando, FL	October	2003
23	Tribo-Metrology of CMP Process and Materials	Rensselaer Polytechnic Institute	Troy, NY	October	2003
24	Tribo-Metrology of Thin Films and Nano-Coatings	McGill University	Montreal, Canada	October	2003
25	Latest Achievements in Tribo-Metrology	University of Leoben	Leoben, Austria	June	2003
26	Latest Achievements in Tribo-Metrology	Vienna Technical University	Vienna, Austria	June	2003
27	Latest Achievements in Tribo-Metrology	Istanbul Technical University	Istanbul, Turkey	June	2003
28	Latest Achievements in Tribo-Metrology	University of North Carolina	Charlotte, NC	February	2003
29	Latest Achievements in Tribo-Metrology	Hunan University	Changsha, China	January	2003
30	Latest Achievements in Tribo-Metrology	Shanghai University	Shanghai, China	January	2003
31	Latest Achievements in Tribology and its Applications	Shanghai Jiao Tong University	Shanghai, China	January	2003
32	Tribo-Metrology of Lubricants and Coatings	DaLian Maritime University	Dalian, China	September	2002
33	Latest Achievements in Tribology and its Applications	JiLin University	Changchun, China	August	2002
34	Latest Achievements in Tribology and its Applications	Lanzhou Institute of Chemical Physics	Lanzhou, China	April	2002
35	Latest Achievements in Tribology and its Applications	Tsinghua University	Beijing, China	March	2002
36	Latest Achievements in Tribology and its Applications	University of South Florida	Tempe, FL	November	2000
37	Tribo-Metrology of Thin Films and Hard Coatings	State University of New York	Stony Brook, NY	January	2000
38	Tribo-Metrology of Thin Films and Soft Coatings	State University of New York	Syracuse, NY	January	2000
39	Tribo-Metrology of Thin Films and Coatings	University of California	Irvine, CA	December	1999
40	Tribo-Metrology of Thin Films and Coatings	California Institute of Technology	Pasadena, CA	September	1999
41	Tribology of Near-Contact Head-Disk Interface	Data Storage Institute	Singapore	June	1998
42	Tribology of Near-Contact Head-Disk Interface	University of California	San Diego, CA	January	1997
43	Advanced Tribology of Magnetic Head-Disk Interface	Santa Clara University	Santa Clara, CA	July - August	1996
44	Advanced Tribology of Magnetic Head-Disk Interface	Santa Clara University	Santa Clara, CA	Septem - Decem	1995
45	Tribology of Near-Contact Head-Disk Interface	University of California	Santa Barbara, CA	June	1992
46	Tribology of Near-Contact Head-Disk Interface	University of California	San Diego, CA	May	1992
47	Latest Achievements in Tribology and its Applications	Georgia Institute of Technology	Atlanta, GA	June	1989
48	Latest Achievements in Tribology and its Applications	Massachussetts Institute of Technology	Cambridge, MA	May	1989
49	Nature of Friction and Frictional Auto-Oscillations	Academic Institute for Applied Mechanics	Moscow, Russia	June	1986
50	Nature of Friction and Frictional Auto-Oscillations	Academic Institute for Machine Sciences	Moscow, Russia	April	1986
51	Friction Optimization in Boundary Lubrication	Academic Institute for Machine Sciences	Moscow, Russia	September	1983
52	Friction Optimization in Boundary Lubrication	Academic Institute for Applied Mechanics	Moscow, Russia	May	1983
53	Friction Optimization in Boundary Lubrication	Bryansk Polytechnic University	Bryansk, Russia	May	1983
54	Friction Optimization in Boundary Lubrication	Soviet Institute for Machinery Standardization	Moscow, Russia	April	1983
55	Friction Optimization in Boundary Lubrication	Leningrad Institute for Precision Mechanics & Optics	Leningrad, Russia	March	1983

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56	Friction Optimization in Boundary Lubrication	Leningrad Polytechnic University	Leningrad, Russia	March	1983
57	Friction Optimization in Boundary Lubrication	Academic Institute for Hard Materials and Coatings	Kiev, Ukraine	September	1982
Corporations					
1	Tribo-Metrology of Thin Films and Coatings	Bharat Heavy Electric	Hyderabad, CA	February	2006
2	Tribo-Metrology of Lubricants	Bharat Petroleum	Mumbai, India	January	2006
3	Tribo-Metrology of Thin Films and Coatings	Western Digital	Fremont, CA	August	2005
4	Tribo-Metrology of Metalworking Fluids and Lubricants	Ecolab	St. Paul, MN	August	2005
5	Latest Achievements in Tribo-Metrology	Salzgitter Mannesman	Salzgitter, Germany	June	2005
6	Latest Achievements in Tribo-Metrology	INA/FAG	Herzogenaurach, Germany	June	2005
7	Latest Achievements in Tribo-Metrology	German Institue for Rubber Technology	Hanover, Germany	June	2005
8	Latest Achievements in Tribo-Metrology	Volvo Technology	Goteburg, Sweden	June	2005
9	Latest Achievements in Tribo-Metrology	IWIS	Munich, Germany	March	2005
10	Tribo-Metrology of Chemical-Mechanical Polishing	Wacker	Burghausen, Germany	March	2005
11	Tribo-Metrology of Chemical-Mechanical Polishing	Infineon	Dresden, Germany	March	2005
12	Tribo-Metrology of Chemical-Mechanical Polishing	STMicroelectronics	Agrate, Italy	March	2005
13	Latest Achievements in Tribo-Metrology	India Oil Corporation	Fahdarabad, India	December	2004
14	Latest Achievements in Tribo-Metrology	Powder Metallurgy R&D Center	Hyderabad, India	December	2004
15	Latest Achievements in Tribo-Metrology	GE Welch R&D Center	Bangalore, India	December	2004
16	Tribo-Metrology of Thin Films and Coatings	Hind HiVacuum	Bangalore, India	December	2004
17	Latest Achievements in Tribo-Metrology	Saint-Gobain Advanced Materials	Northboro, MA	December	2004
18	Tribo-Metrology of Thin Films and Coatings	SAE Magnetics	Hong Kong	October	2004
19	Tribo-Metrology of Biomedical Materials and Devices	Guidant	St. Paul, MN	October	2004
20	Tribo-Metrology of Biomedical Materials and Devices	Medtronic	Minneapolis, MN	October	2004
21	Tribo-Metrology of Chemical-Mechanical Polishing	Matsushita Electric	Toyama, Japan	September	2004
22	Multi-Sensing Tribo-Micro/Nano-Metrology	Yamaha	Hamamatsu, Japan	September	2004
23	Latest Achievements in Tribo-Metrology	Eagle Industry	Tsukuba, Japan	September	2004
24	Tribo-Metrology of Chemical-Mechanical Polishing	Micron Technology	Boise, ID	September	2004
25	Tribo-Metrology of Chemical-Mechanical Polishing	LSI Logic	Gresham, OR	September	2004
26	Tribo-Metrology of Chemical-Mechanical Polishing	Namiki	Tokyo, Japan	August	2004
27	Tribo-Metrology of Chemical-Mechanical Polishing	Hitachi Chemical	Ibaraki, Japan	August	2004
28	Latest Achievements in Tribo-Metrology	Caterpillar	Peoria, IL	July	2004
29	Tribo-Metrology of Chemical-Mechanical Polishing	Rohm & Haas	Newark, DE	May	2004
30	Tribo-Metrology of Chemical-Mechanical Polishing	Novellus	Chandler, AZ	April	2004
31	Latest Achievements in Tribo-Metrology	Baosteel	Shanghai, China	March	2004
32	Tribo-Metrology of Chemical-Mechanical Polishing	JSR Corporation	Yokkaichi, Japan	March	2004
33	Latest Achievements in Tribo-Metrology	Lord	Cary, NC	February	2004
34	Tribo-Metrology of Chemical-Mechanical Polishing	Hitachi	Tokyo, Japan	October	2003
35	Latest Achievements in Tribo-Metrology	Miba	Laakirchen, Austria	June	2003
36	Latest Achievements in Tribo-Metrology	Arcelik	Istanbul, Turkey	June	2003
37	Latest Achievements in Tribo-Metrology	Korea Testing Laboratory	Seoul, South Korea	May	2003
38	Tribo-Metrology of Chemical-Mechanical Polishing	Samsung Corning	Suwon, South Korea	May	2003
39	Tribo-Metrology of Chemical-Mechanical Polishing	Samsung Electronics	Yongin, South Korea	May	2003
40	Tribo-Metrology of Chemical-Mechanical Polishing	Hynics Semiconductors	Icheon, South Korea	May	2003
41	Latest Achievements in Tribo-Metrology	NASA Goddard Space Center	Greenbelt, MD	April	2003
42	Tribo-Metrology of Chemical-Mechanical Polishing	Intel	Albuquerque, NM	April	2003
43	Tribo-Metrology of Electrical Connectors	National Electrical Carbon	Greenville, SC	February	2003

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44	Tribo-Metrology of Metalworking Fluids and Lubricants	Lubrizol	Spartanburg, SC	February	2003
45	Tribo-Metrology of Electrical Connectors	Morganite	Dunn, NC	February	2003
46	Tribo-Metrology of Biomedical Materials and Skin	Unilever	Edgewater, NJ	January	2003
47	Latest Achievements in Tribo-Metrology	Aerospace Research # 4	Hohhot, China	January	2003
48	Tribo-Metrology of Polymers and Elastomers	Shanghai Polymer Research Center	Shanghai, China	January	2003
49	Tribo-Metrology of Biomedical Devices and Materials	DePuy Orthopedics	Warsaw, IN	November	2002
50	Tribo-Metrology of Chemical-Mechanical Polishing	Cabot Microelectronics	Aurora, IL	November	2002
51	Tribo-Metrology of Chemical-Mechanical Polishing	NEC	Roseville, CA	November	2002
52	Tribo-Metrology of Chemical-Mechanical Polishing	Intel	Santa Clara, CA	October	2002
53	Tribo-Metrology of Chemical-Mechanical Polishing	Strasbaugh	San Luis Obispo, CA	August	2002
54	Tribo-Metrology of Chemical-Mechanical Polishing	SpeedFam-IPEC	Chandler, AZ	August	2002
55	Tribo-Metrology of Lubricants and Coatings	1st Chinese Automobile Company	Changchun, China	August	2002
56	Tribo-Metrology of Biomedical Materials and Skin	Procter & Gamble	Cincinnati, OH	June	2002
57	Tribo-Metrology of Chemical-Mechanical Polishing	Rodel	Phoenix, AZ	April	2002
58	Tribo-Metrology of Chemical-Mechanical Polishing	NEC	Shanghai, China	March	2002
59	Tribo-Metrology of Biomedical Devices and Materials	Guidant	Menlo Park, CA	March	2002
60	Tribo-Metrology of Polymers and Elastomers	Advanced Elastomer Systems	Akron, OH	January	2002
61	Latest Achievements in Tribo-Metrology	NASA Glenn Research Center	Cleveland, OH	January	2002
62	Tribo-Metrology of Metalworking Fluids and Lubricants	Milacron	Cincinnati, OH	January	2002
63	Tribo-Metrology of Sliding and Rolling Bearings	Timken	Canton, OH	January	2002
64	Tribo-Metrology of Chemical-Mechanical Polishing	IBM Semiconductors	Fishkill, NY	October	2001
65	Tribo-Metrology of Chemical-Mechanical Polishing	IBM Wattson Research Center	Yorktown Heights, NY	October	2001
66	Tribo-Metrology of Lubricants and Coatings	Ecolab	St.Paul, MN	June	2001
67	Tribo-Metrology of Biomedical Devices and Materials	St. Jude Medical	St. Paul, MN	June	2001
68	Tribo-Metrology of Chemical-Mechanical Polishing	Intel	Hillsboro, OR	May	2001
69	Tribo-Metrology of Chemical-Mechanical Polishing	Cabot Microelectronics	Aurora, IL	February	2001
70	Tribo-Metrology of Chemical-Mechanical Polishing	Ebara	Fujisawa, Japan	February	2001
71	Tribo-Metrology of Chemical-Mechanical Polishing	Toshiba	Shizuoka, Japan	February	2001
72	Tribo-Metrology of Chemical-Mechanical Polishing	Sony	Kanagawa, Japan	January	2001
73	Tribo-Metrology of Chemical-Mechanical Polishing	LSI Logic	Ibaraki, Japan	January	2001
74	Tribo-Metrology of Chemical-Mechanical Polishing	NEC	Kanagawa, Japan	January	2001
75	Tribo-Metrology of Chemical-Mechanical Polishing	Greene, Tweed & Company	Kulpsville, PA	December	2000
76	Tribo-Metrology of Chemical-Mechanical Polishing	Rodel	Newark, DE	December	2000
77	Tribo-Metrology of Biomedical Devices and Materials	United States Surgical	North Haven, CT	December	2000
78	Latest Achievements in Tribo-Metrology	International Sematech	Austin, TX	November	2000
79	Tribo-Metrology of Sliding and Rolling Bearings	SKF	Utrecht, Netherlands	September	2000
80	Tribo-Metrology of Chemical-Mechanical Polishing	SpeedFam-IPEC	Chandler, AZ	August	2000
81	Tribo-Metrology of Lubricants and Coatings	Honeywell Aerospace	Tempe, AZ	August	2000
82	Latest Achievements in Tribo-Metrology	Fuji Electric	Nagano, Japan	July	2000
83	Latest Achievements in Tribo-Metrology	Sony	Sendai, Japan	July	2000
84	Latest Achievements in Tribo-Metrology	Mitsubishi Chemical	Mizushima, Japan	July	2000
85	Latest Achievements in Tribo-Metrology	Hitachi	Ibaraki, Japan	July	2000
86	Tribo-Metrology of Lubricants and Coatings	Verbatim	San Diego, CA	April	2000
87	Tribo-Metrology of Biomedical Devices and Materials	Orthopeadic Research Center	Los Angeles, CA	April	2000
88	Latest Achievements in Tribo-Metrology	3M	St.Paul, MN	February	2000
89	Latest Achievements in Tribo-Metrology	Imation	Oakdale, MN	February	2000

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90	Tribo-Metrology of Lubricants	Cargill	Minneapolis, MN	February	2000
91	Tribo-Metrology for Biomedical Devices	SurModics	St.Paul, MN	February	2000
92	Tribo-Metrology of Thin Films and Coatings	Essilor	Paris, France	January	2000
93	Tribo-Metrology of Thin Films and Coatings	Balzers	Liechtenstein	January	2000
94	Tribo-Metrology of Lubricants and Coatings	DuPont	Wilmington, DE	January	2000
95	Tribo-Metrology of Thin Films and Coatings	US Army Benet Lab	Watervliet, NY	January	2000
96	Tribo-Metrology of Thin Films and Coatings	Sulzer Metco	Westbury, NY	January	2000
97	Tribo-Metrology of Thin Films and Coatings	Gillette	Boston, MA	January	2000
98	Latest Achievements in Tribo-Metrology	Rodel	Newark, DE	January	2000
99	Latest Achievements in Tribo-Metrology	YTC America	Camarillo, CA	December	1999
100	Tribo-Metrology of Thin Films and Coatings	Imation	Camarillo, CA	December	1999
101	Tribo-Metrology of Lubricants	Castrol Industrial	Downers Grove, IL	October	1999
102	Tribo-Metrology of Thin Films and Coatings	Honeywell Aerospace	Torrance, CA	September	1999
103	Latest Achievements in Tribo-Metrology	Jet Propulsion Laboratory	Pasadena, CA	September	1999
104	Tribo-Metrology of Magnetic Head-Disk Interface	Hitachi	Odawara, Japan	April	1999
105	Tribo-Metrology of Magnetic Head-Disk Interface	Matsushita Electric	Osaka, Japan	April	1999
106	Tribo-Metrology of Magnetic Head-Disk Interface	Fujitsu	Kawasaki, Japan	April	1999
107	Tribo-Metrology of Magnetic Head-Disk Interface	Mitsubishi Chemical	Yokohama, Japan	April	1999
108	Tribo-Metrology of Magnetic Head-Disk Interface	Showa Denko	Chiba, Japan	April	1999
109	Tribo-Metrology of Magnetic Head-Disk Interface	NEC	Kanagawa, Japan	April	1999
110	Tribo-Metrology of Magnetic Head-Disk Interface	Yamaha	Hamamatsu, Japan	April	1999
111	Latest Achievements in Tribo-Metrology	Hewlett Packard	Vancouver, WA	March	1999
112	Latest Achievements in Tribo-Metrology	FormFactor	Livermore, CA	January	1999
113	Tribo-Metrology of Thin Films and Coatings	Iomega	Roy, UT	December	1998
114	Tribo-Metrology of Lubricants	Castrol Industrial	Chicago, IL	December	1998
115	Tribo-Metrology of Magnetic Head-Disk Interface	Seagate Technology	Longmont, CO	September	1998
116	Tribo-Metrology of Magnetic Head-Disk Interface	Seagate Technology	Bloomington, MN	September	1998
117	Tribo-Metrology of Magnetic Head-Disk Interface	Fujitsu	Kawasaki, Japan	September	1998
118	Tribo-Metrology of Magnetic Head-Disk Interface	Sony	Shinagawa, Japan	September	1998
119	Tribo-Metrology of Magnetic Head-Disk Interface	Read-Rite Sumitomo	Osaka, Japan	September	1998
120	Tribo-Metrology of Magnetic Head-Disk Interface	Sharp	Yokohama, Japan	September	1998
121	Tribo-Metrology of Magnetic Head-Disk Interface	Fuji Electric	Nagano, Japan	September	1998
122	Tribo-Metrology of Magnetic Head-Disk Interface	SilMag	Grenoble, France	June	1998
123	Tribo-Metrology of Magnetic Head-Disk Interface	Seagate Technology	Singapore	June	1998
124	Tribo-Metrology of Magnetic Head-Disk Interface	Hoya	Singapore	June	1998
125	Tribo-Metrology of Magnetic Head-Disk Interface	Mitsubishi Chemical	Singapore	June	1998
126	Testing and Analysis of Magnetic Disk Drives	Hitachi	Santa Clara, CA	May	1998
127	Tribo-Metrology of Magnetic Head-Disk Interface	Iomega	San Diego, CA	March	1998
128	Latest Achievements in Tribo-Metrology	Dana Corporation	Ottawa Lake, OH	November	1997
129	Tribo-Metrology of Magnetic Head-Disk Interface	Seagate Technology	Clonmel, Ireland	September	1997
130	Tribo-Metrology of Magnetic Head-Disk Interface	Trace Storage	Hsinchu, Taiwan	July	1997
131	Tribo-Metrology of Magnetic Head-Disk Interface	SAE Magnetics	Hong Kong	July	1997
132	Tribo-Metrology of Magnetic Head-Disk Interface	Matsushita Electric	Osaka, Japan	July	1997
133	Tribo-Metrology of Magnetic Head-Disk Interface	Iomega	Roy, UT	May	1997
134	Tribo-Metrology of Magnetic Head-Disk Interface	Hitachi	Odawara, Japan	April	1997
135	Tribo-Metrology of Magnetic Head-Disk Interface	Fujitsu	Atsugi, Japan	April	1997
136	Tribo-Metrology of Magnetic Head-Disk Interface	Fuji Electric	Nagano, Japan	April	1997
137	Tribo-Metrology of Magnetic Head-Disk Interface	Mitsubishi Chemical	Mizushima, Japan	April	1997
138	Tribo-Metrology of Magnetic Head-Disk Interface	IBM Almaden Research Center	San Jose, CA	February	1997
139	Tribo-Metrology of Magnetic Head-Disk Interface	Trace Storage	Hsinchu, Taiwan	January	1997

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140	Testing and Analysis of Magnetic Disk Drives	Toshiba	Irvine, CA	November	1996
141	Testing and Analysis of Magnetic Disk Drives	Hitachi	Brisbane, CA	August	1996
142	Testing and Analysis of Magnetic Disk Drives	Dell Computer	Austin, TX	August	1996
143	Tribo-Metrology of Magnetic Head-Disk Interface	Samsung	Korea	July	1996
144	Tribo-Metrology of Magnetic Head-Disk Interface	Hyundai	Korea	July	1996
145	Tribo-Metrology of Magnetic Head-Disk Interface	Hoya	Singapore	April	1996
146	Tribo-Metrology of Magnetic Head-Disk Interface	Seagate Technology	Singapore	April	1996
147	Tribo-Metrology of Magnetic Head-Disk Interface	Mitsubishi Chemical	Singapore	April	1996
148	Tribo-Metrology of Magnetic Head-Disk Interface	Akashic Memories	San Jose, CA	December	1995
149	Advanced Tribology of Magnetic Head-Disk Interface	Seagate Technology	Bangkok, Thailand	November	1995
150	Advanced Tribology of Magnetic Head-Disk Interface	Hitachi	Odawara, Japan	November	1995
151	Advanced Tribology of Magnetic Head-Disk Interface	Matsushita Electric	Osaka, Japan	November	1995
152	Advanced Tribology of Magnetic Head-Disk Interface	Apple Computer	Cupertino, CA	July	1995
153	Testing and Analysis of Magnetic Disk Drives	MTI	Anaheim, CA	May	1995
154	Micro-Tribology of Magnetic Head-Disk Interface	Corning Inc.	Corning, NY	April	1995
155	Micro-Tribology of Magnetic Head-Disk Interface	NTT	Tokyo, Japan	April	1995
156	Micro-Tribology of Magnetic Head-Disk Interface	NEC	Kanagawa, Japan	April	1995
157	Micro-Tribology of Magnetic Head-Disk Interface	Fuji Electric	Kanagawa, Japan	April	1995
158	Micro-Tribology of Magnetic Head-Disk Interface	Fujitsu	Atsugi, Japan	April	1995
159	Micro-Tribology of Magnetic Head-Disk Interface	Seagate Technology	Oklahoma City, OK	February	1995
160	Micro-Tribology of Magnetic Head-Disk Interface	Seagate Technology	Scotts Valley, CA	January	1995
161	Micro-Tribology of Magnetic Head-Disk Interface	Seagate Technology	Oklahoma City, OK	December	1994
162	Micro-Tribology of Magnetic Head-Disk Interface	Corning Inc.	Corning, NY	November	1994
163	Micro-Tribology of Magnetic Head-Disk Interface	Quantum	Milpitas, CA	November	1994
164	Micro-Tribology of Magnetic Head-Disk Interface	Samsung	San Jose, CA	April	1994
165	Micro-Tribology of Magnetic Head-Disk Interface	Censtor	San Jose, CA	November	1993
166	Micro-Tribology of Magnetic Head-Disk Interface	StorMedia	Santa Clara, CA	October	1993
167	Micro-Tribology of Magnetic Head-Disk Interface	Showa Denko	Chiba, Japan	August	1993
168	Tribology of Near-Contact Head-Disk Interface	Maxtor	Longmont, CO	February	1993
169	Tribology of Near-Contact Head-Disk Interface	Hutchinson Technology	Hutchinson, MN	August	1992
170	Tribology of Near-Contact Head-Disk Interface	Maxtor	San Jose, CA	November	1992
171	Tribology of Near-Contact Head-Disk Interface	Showa Denko	Chiba, Japan	October	1992
172	Tribology of Near-Contact Head-Disk Interface	Yamaha	Hamamatsu, Japan	October	1992
173	Advanced Tribology of Magnetic Head-Disk Interface	Read-Rite	Milpitas, CA	February	1992
174	Stiction Phenomenon in Head-Disk Interface	IBM Storage Systems	San Jose, CA	April	1991
175	Advanced Tribology of Magnetic Head-Tape Interface	IBM Storage Systems	Tucson, AZ	April	1990
176	Latest Achievements in Tribology and its Applications	IBM Almaden Research Center	San Jose, CA	May	1989
177	Latest Achievements in Tribology and its Applications	IBM Storage Systems	San Jose, CA	May	1989
178	Friction Optimization in Boundary Lubrication	Moscow Center for Machine Tools and Robotics	Moscow, Russia	March	1986
179	Friction Optimization in Boundary Lubrication	Leningrad Machine Tool Company	Leningrad, Russia	November	1985
180	Durability Evaluation of Spur Gears	Odessa Machine Tool Company	Odessa, Ukraine	June	1981

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	Civil Action No. 04-12457 PBS

RESPONSIVE EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE CONCERNING NON-INFRINGEMENT OF U.S. PATENT NO. 5,314,446 AND OTHER MATTERS

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his responsive expert report concerning non-infringement and other matters as follows.

I. INTRODUCTION

I have been retained, through Dickstein Shapiro Morin & Oshinsky LLP, as a technical expert by Arthrex, Inc. ("Arthrex") and Pearsalls, Ltd. ("Pearsalls") (together "Defendants") to review U.S. Patent No. 5,314,446 ("the '446 patent"), its prosecution history, the Expert Report of Dr. David Brookstein ("Brookstein Report"), reports prepared by the Center for Tribology, Inc., as well as by Dr. Robert Burks, and certain other materials, and to provide my opinion on issues raised by Dr. Brookstein's report, including: i) whether a person of ordinary skill in the art in February 1992 would have understood the term "PE," as described and claimed in the '446 patent, to include ultra high molecular weight polyethylene ("UHMWPE"); ii) what a person of ordinary skill in the art in February 1992 would have understood to be the basic and novel characteristics of the invention described and claimed in the '446 patent; iii) whether the addition of a coating, as used on Arthrex's FiberWire sutures, affects those basic and novel characteristics; iv) whether the addition of nylon, as used in Arthrex's TigerWire sutures, affects those basic and novel characteristics; v) whether the addition of an adhesive, as used on Arthrex's FiberStick sutures, affects those basic and novel characteristics, vi) whether the braids produced by Pearsalls are suitable for uses other than FiberWire suture; and vii) whether claim 9 of the '446 patent, which I understand has been newly asserted by DePuy Mitek, is invalid in view of prior art. I am being compensated at a rate of $1000.00 per day.

I expect to be called to provide expert testimony at trial regarding opinions formed resulting from my investigation of these issues, any matters set forth in this report, and rebuttal of any matters raised by Plaintiff DePuy Mitek. This report includes my opinions regarding these matters. I specifically reserve the right to formulate and offer additional opinions based on any other reports received from DePuy Mitek, or on any additional information that may be provided, and I likewise reserve the right to supplement my opinions based on future court rulings, agreements between the parties, and additional evidence submitted by either party prior to or during trial. Opinions formed are covered below in Section VI. Documents reviewed and considered are identified in Section III and Ex. 1.

II. SUMMARY OF MY OPINIONS

Based upon my review and consideration of the materials identified in Ex. 1, it is my opinion that a person of ordinary skill in the art, in February 1992, would not understand the term "PE," as described and claimed in the '446 patent, to include UHMWPE.

It is also my opinion that a person of ordinary skill in the art, in February 1992, would have understood the basic and novel characteristics of the invention described and claimed in the '446 patent to be a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties.

It is further my opinion that the addition of a coating, as used on Arthrex's FiberWire suture, affects the basic and novel characteristics of the invention described and claimed in the '446 patent. It is also my opinion that the addition of nylon, as used in Arthrex's TigerWire suture, affects the basic and novel characteristics of the invention described and claimed in the '446 patent. And it is my opinion that the addition of an adhesive, as used on Arthrex's FiberStick suture, affects the basic and novel characteristics of the invention described and claimed in the '446 patent.

It is also my opinion that the unsterilized and untipped braids of the type manufactured by Pearsalls are suitable for uses other than as FiberWire suture. For example, the same braids are suitable for use as fishing line.

It is further my opinion that U.S. Patent No. 4,610,688, ("the '688 patent"), when combined with U.S. Patent No. 5,120,802 ("the '802 patent"), and/or the general teachings of the art, includes every limitation of newly asserted claim 9 of the '446 patent. It is also my opinion that in the event that the Court were to determine that UHMWPE does fall within the meaning of PE, as described and claimed in the '446 patent, then the '575 patent includes every limitation of newly asserted claim 9 of the '446 patent. Further, if the Court does include UHMWPE within the meaning of PE, then it is also my opinion that the combination of UK Patent Application No. 2,218,312A to Burgess ("the Burgess application") and i) Cohan, et al., *An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture,* Arch Ophthalmol – Vol. 103, December 1985

("the Cohan article"); ii) *Dyneema SK60, High strength/ high modulus fiber, Properties & Applications* ("the DSM brochure"); and/or iii) either one of U.S. Patent Nos. 4,563,392 or 4,543,286, both to Harpell et al. ("the Harpell patents"), would include every limitation of newly asserted claim 9 of the '446 patent.

III. REVIEW AND USE OF DOCUMENTS AND OTHER MATERIALS

The documents and things I have reviewed and considered in the preparation of this report are the '446 patent, its prosecution history, the Expert Report of Dr. David Brookstein, reports prepared by the Center for Tribology, Inc., as well as by Dr. Robert Burks, Arthrex's Responses to DePuy Mitek's Interrogatories, DePuy Mitek's Responses to Arthrex's Interrogatories, U.S. Patents Nos. 5,318,575, 4,610,688 and 5,120,802, the Burgess application, the Cohan article, the DSM brochure, the Harpell patents, various documents of DePuy Mitek, Ethicon, Arthrex and Pearsalls, and the documents and things identified at Ex. 1. I have also relied upon my experience and well-known principles in the manufacturing and processing fields of fibers that can be used for biomedical applications, and discussions with Bill Benavitz of Arthrex, Norman Gitis of the Center for Tribology, Inc. and John Witherspoon, who I understand is a legal expert retained in this case.

IV. QUALIFICATIONS

My qualifications as an expert witness are listed in my Curriculum Vitae attached as Ex. 2.

V. THE '446 PATENT AND PROSECUTION HISTORY

While my first report included a section discussing the specification and the prosecution history of the '446 patent, I believe it is helpful to repeat it, as necessary, in this report, together with other information, to the extent it is relevant to my opinions in this report.

The '446 patent is directed to heterogeneous braids that can be used as a component of either surgical suture or ligatures. Ex. 3 at col. 1, ll. 6-7. The '446 patent describes the benefits of a braided multifilament over a monofilament. Some of those benefits include enhanced pliability, knot security and tensile strength when compared with a monofilament. Ex. 3 at col. 1, ll. 8-10. As the '446 patent describes, the enhanced pliability of a braided multifilament results from the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament.

The '446 patent then describes that although an improvement over monofilaments, braided multifilaments still often presented certain problems when coated.

The '446 patent then goes on to describe that the prior art attempts to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on braid properties. The specification suggests the use of braided multifilaments made of fibers composed of highly lubricious polymers as a solution. The specification explains

that while such braids will be highly pliable, they will also be relatively weak and unusable for most suture applications. Ex. 3 at col. 2, ll. 22-25.

The proposed solution described in the '446 patent is a heterogeneous braid made up of two dissimilar materials. According to the specification, the braid is made up of a first fiber-forming material mechanically interlocked or weaved with a second fiber-forming material. The specification also states that the first fiber-forming material is a lubricious material, and that the second fiber-forming material is added for strength. The fact that the first fiber-forming materials are lubricious but too weak for most suture applications is further made clear by the specification which states that "a volume fraction [of lubricating yarns] above about 80% may adversely affect the overall strength of the braid." As described throughout the specification, there is a tradeoff between the properties of the two materials – one being lubricious but weak, the other being added for strength. The specification further recognizes that gains in handleability/pliability outweigh any loss of strength.

The specification also repeatedly states that the advantage of the above-described braid construction is that the braid exhibits improved handleability and pliability without appreciably sacrificing its physical properties. Ex. 3 at col. 2, ll. 32 – 37; ll. 62 – 66; col. 6, ll. 7 – 8.

Claim 1 of the '446 patent is to a surgical suture, the surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous

and discrete yarns in a sterilized and braided construction. Claim 1 also states that at least one yarn from the first set is in direct intertwining contact with a yarn from the second set. Claim 1 also states that each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material and that each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material. Claim 1 further defines the first fiber-forming materials as one of PTFE, FEP, PFA, PVDF, PETFE, PP and PE, and further defines the second fiber-forming materials as one of PET, nylon and aramid. The other claims that are asserted add additional limitations.

The application for the '446 patent was filed on February 19, 1992, as U.S. Patent Application No. 07/838,511 ("the '511 application"). At the time the '511 application was filed, four inventors were listed – Alastair W. Hunter, Arthur Taylor, Jr., Mark Steckel and Dennis D. Jamiolkowski.

During prosecution of the '511 application, the patent examiner at the U.S. Patent and Trademark Office ("PTO") issued a restriction requirement on July 8, 1992. I understand from Defendants' legal expert that a restriction requirement is issued when the examiner believes that a patent application contains at least two different inventions (e.g., in the case of the '446 patent, a heterogeneous braid and a surgical suture). The applicants must then select one invention which remains in the application.

In issuing the restriction requirement, the patent examiner asserted that the '511 application contained two different inventions – i) a heterogeneous braid and ii) a

surgical suture, and that the applicants were required to select one of those two inventions which would remain in the '511 application. The examiner also stated that the heterogeneous braid invention was "an intermediate product [that] is useful to make other than the final product [of a surgical suture]." The examiner then stated that the heterogeneous braid invention was "deemed to be useful as a fishing line." Ex. 4 at 2. The applicants selected the surgical suture inventions (i.e., claims 21-24).

Further, during prosecution of the '511 application, the patent examiner at the U.S. Patent and Trademark Office ("PTO") cited the Burgess patent application and rejected the then-pending claims (i.e., claims 21-24). The Burgess patent application disclosed a heterogeneous braided fishing line comprised of two dissimilar materials – DYNEEMA (which is a brand name for UHMWPE) and polyester and/or nylon. Ex. 4 at 1-2.

The examiner found that the Burgess application disclosed a braided fishing line made up of two polymers with different properties, and therefore, it was "known to braid filaments of two dissimilar polymers together to form a structure which embodies the desirable properties of each fiber." Ex. 4 at 4. Thus, it was known to make this type of braid for these purposes. The examiner reasoned that it would have been obvious to a person of ordinary skill in the art at the time to use a heterogeneous braid for a suture since: i) braided sutures were, at the time, well known in the art; ii) many of the requirements of sutures were comparable to those of fishing line – strength, low

stretchability, etc.; and iii) many of the same materials were used to make both fishing lines and sutures. Ex. 4 at 5.

In response to the rejection based on the Burgess application, Ethicon's attorney recognized that UHMWPE had great strength properties, but argued that it would be bad to use UHMWPE for a suture because it has low elongation and poor knot strength properties. The Ethicon attorney also asserted that if a medical designer were to actually build a surgical suture using the braided combination of UHMWPE and polyester and/or nylon – the combination disclosed in the Burgess application - then "he would inevitably design an unacceptable suture," (Ex. 5 at 3-4) and that the braided combination disclosed in the Burgess application would have "poor knot strength properties." Ex. 5 at 2-3. The '511 application eventually issued as the '446 patent.

VI. OPINIONS

A. "PE" as described and claimed in the '446 patent does not include UHMWPE

I understand from my discussions with John Witherspoon that the Court will ultimately interpret the meaning of the claim language. In order to assist the Court with interpreting the claim language, I am providing in this section of my report an explanation of why I believe the '446 patent does not include UHMWPE and why a person of ordinary skill in the art would not understand the term "PE," as it is described and claimed in the '446 patent to include UHMWPE. As I mentioned in my first report, it is my opinion that a person of ordinary skill in the art, in February 1992,

had an undergraduate degree in engineering or science and several years (e.g., approximately 3-5) experience with manufacturing and/or processing of fibers and sutures which can be used for biomedical applications.

It is my opinion that a person of ordinary skill in the art would not understand that the term "PE," as described and claimed in the '446 patent, includes UHMWPE. The reasons for my opinion include the same reasons I previously mentioned as to why I believe the '446 patent specification does not reasonably convey to one of ordinary skill in the art that the inventors had possession of UHMWPE.

I add some additional comments. It is my understanding, from the legal expert, that the prosecution history of a patent plays a role during the claim construction process. I have reviewed the prosecution history of the '511 application and it is my opinion that a person of ordinary skill in the art would understand that the applicants argued that UHMWPE was *not* part of their invention.

As I described above, in response to the patent examiner citing the Burgess application in rejecting claims 21-24, Ethicon's attorney argued that it would be bad to use UHMWPE for a suture because it has low elongation and poor knot strength properties. The Ethicon attorney also asserted that if a medical designer were to actually build a surgical suture using the braided combination of UHMWPE and polyester and/or nylon – the combination disclosed in the Burgess application – the braid would have "poor knot strength properties." (Ex. 5 at 2, 3) and "he would

inevitably design an unacceptable suture." Ex. 5 at 3-4. It is my opinion that a person of ordinary skill in the art reading these remarks made by Ethicon's attorney would clearly understand that it was Ethicon's position that UHMWPE is *not* part of the invention of the '446 patent.

Another reason why I believe UHMWPE is not included within the meaning of "PE" as it is described and claimed in the '446 patent is because there is no mention at all within the '446 patent that "PE" can be used to impart strength to the braid. It was known at the time that UHMWPE was an extremely strong material, and as I explained in my previous report, there were several suggestions to use UHMWPE for suture because of its strength component. The evidence in this case shows that Ethicon and the inventors knew that UHMWPE has great strength. The Ethicon attorney, when responding to the Burgess rejection, specifically states that UHMWPE "has great strength properties." In addition, Dr. Steckel testified that during the development work that lead to the '446 patent he knew that UHMWPE had great strength. Ex. 6 at 190:18-21. If the inventors intended for the described "PE" to include UHMWPE, one would expect that they would have specifically mentioned "PE" as a material that can be used to impart strength to the suture. Yet there is absolutely no mention of "PE" when the patent discusses materials that add strength to the suture. The absence of any such discussion, particularly in light of Ethicon's knowledge, would strongly suggest to

a person of ordinary skill in the art that the inventors did not mean to convey that UHMWPE fell within the meaning of "PE."

I see that Dr. Brookstein assumed that the meaning of "PE" within the '446 patent includes UHMWPE. Brookstein Report at 9. For the reasons I describe above, it is my opinion that this is an incorrect assumption.

I have also read DePuy Mitek's third supplemental response to Arthrex's Interrogatory No. 2. I understand that DePuy Mitek has asserted that Arthrex's statements regarding the meaning of "PE" within the context of the '446 patent are "wrong" and that "Arthrex's citations are to certain preferred embodiments." I disagree.

It is my opinion that a person of ordinary skill in the art reviewing, for example, the background portion of the '446 patent specification would understand that the discussion is not limited to a preferred embodiment when it describes that "braids of highly lubricious polymers" will be highly pliable but they will also be relatively weak and unusable for most suture applications. Ex. 3 at col. 2, ll. 22-25. This general description of highly lubricious polymers is consistent with what was known in the art about general purpose PE and inconsistent with what was known in the art about UHMWPE. It is also my opinion that the specification is generally describing lubricious polymers where it states "a volume fraction of *lubricating yarns* below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about

80 percent may adversely affect the overall strength of the braid." Ex. 3 at col. 4, ll. 52-54. [Emphasis added.] The entirety of the discussion in the patent specification explains that there is a tradeoff between the two fiber-forming materials – lubricious but weak versus strong. The point made by the inventors is that gains in pliability and handleability by using the combination of lubricious, but weak materials with a stronger material outweighs the loss of suture strength resulting from combining a weaker lubricious material with the stronger material. These observations in the specification go far beyond the "preferred embodiment."

B. There is a substantial difference between UHMWPE and the first fiber-forming materials of claim 1 of the '446 patent

I understand that Dr. Brookstein contends that if UHMWPE is not included within the meaning of "PE" of claim 1 of the '446 patent, and there is no literal infringement, then there is infringement under the doctrine of equivalents. I have been informed by the legal expert that in order for infringement to be found under the doctrine of equivalents, the difference between the claim limitation and the alleged "equivalent" portion of the accused product must be insubstantial. For the reasons described below, it is my opinion that the difference between UHMWPE and any of the first fiber-forming materials of claim 1 of the '446 patent is substantial.

For example, as I stated in my first report, the '446 patent describes that the braid is made up of a first fiber-forming material mechanically interlocked or weaved with a second fiber-forming material. The materials described as first fiber-forming materials

are PTFE, FEP, PFA, PVDF, PETFE, PP and PE. The materials described as second fiber-forming materials are PET, nylon and aramid.

The specification also states that the first fiber-forming materials are lubricious materials that act as lubricating yarns to improve the overall pliability and handling characteristics of the braid. The specification explains that these lubricious materials are too weak to be used alone for most suture applications, and therefore, the second fiber-forming materials are added to improve the overall strength of the braid.

The description in the specification of the first fiber-forming materials is very different from UHMWPE. Unlike the first fiber-forming materials, which are described as being lubricious but relatively weak, UHMWPE is a well-known, highly specialized fiber material with strength properties that are far superior to those of any of the first fiber-forming materials of claim 1, including general purpose PE. Thus, it is my opinion that the difference between UHMWPE and the first fiber-forming materials is substantial.

In addition, while the specification describes that the second fiber-forming materials of claim 1 of the '446 patent are added for strength, it is the UHMWPE that is added to Arthrex's FiberWire suture for increasing its strength. Even Dr. Brookstein recognizes that fact. Brookstein Report at ¶ 63. This is the exact opposite of what the '446 patent describes. I find this to be another substantial difference.

Further, when Arthrex and Pearsalls developed the FiberWire suture, Arthrex created an entirely new category of medical products called high-strength suture. Prior to FiberWire, there was no such product on the market. It is the UHMWPE that makes FiberWire so strong. As I previously mentioned, there is no indication at all within the '446 patent that a high-strength suture was even contemplated by the inventors. To the contrary, the inventors had conceded the fact that there was a tradeoff necessary in having a suture that had better handleability and pliability – that tradeoff was lower strength. That is why the specification repeatedly states that the object of the invention is to achieve better handleability and pliability without appreciably sacrificing physical characteristics, including most specifically, strength. Nowhere is there any description or teaching within the '446 patent that the resulting suture will have strength that is far superior to the prior art sutures identified in the patent. In my opinion, this is another substantial difference.

Putting it in terms of the function/way/result test, as did Dr. Brookstein, it is my opinion that the difference between the function performed by the UHMWPE in FiberWire is very different than that of the first fiber-forming materials of claim 1 of the '446 patent. As I stated above, the function performed by UHMWPE in FiberWire is to impart tremendous strength to the FiberWire suture, whereas the function performed by the first fiber-forming materials is to add lubricity with the recognition that these materials will detract from the strength of the resulting suture. For these same reasons,

it is also my opinion that the way in which the UHMWPE performs in Arthrex's FiberWire suture is substantially different from the way in which the first fiber-forming materials perform in the suture of claim 1 of the '446 patent.

It is further my opinion that the result obtained by substituting UHMWPE for the first fiber-forming materials is substantially different. As I stated earlier, when Arthrex and Pearsalls developed FiberWire, Arthrex introduced the first high-strength suture into the marketplace. There is no indication within the '446 patent that such a high-strength suture was contemplated. If it were, one would expect it to be mentioned in the specification, especially since such a suture would be far superior to any suture that was known at the time, at least for the orthopedic applications for which FiberWire is used. Since the use of UHMWPE to impart strength results is a very different suture than that contemplated by using the first fiber-forming materials of the '446 patent, this is another substantial difference.

Dr. Brookstein appears to state that as long as a material used for the first set of yarns contributes a property that is different than a yarn from the second set, that material is equivalent to the "first fiber-forming material" of claim 1 of the '446 patent. Brookstein Report at 20-23. It is my opinion that this can not be true since it would mean that any suture having two different materials braided together in direct intertwining contact would fall within the claims of the '446 patent. As I understand it, the PTO examiner rejected a claim this broad. Ex. 4 at 4.

C. UHMWPE is used in FiberWire to impart strength and PET is used in FiberWire to improve handleability

As I previously mentioned, the specification of the '446 patent describes that the first fiber-forming materials are added to improve suture handleability and that such materials are too weak for most suture applications. It is the second fiber-forming materials that are added for increased strength. The way in which the individual materials act in FiberWire is the opposite. UHMWPE that is added for strength and the PET is added to improve knot tying – a well-known handleability characteristic.

D. The basic and novel characteristics described in the '446 patent are a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties

I have been asked to provide my opinion regarding what a person of ordinary skill in the art in February 1992 would understand to be the basic and novel characteristics described in the '446 patent. It is my opinion that a person of ordinary skill in the art, in February 1992, reading the specification of the '446 patent would understand the basic and novel characteristics to be a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification. Ex. 3 at col. 2, ll. 32 – 37; ll. 62 – 66; col. 6, ll. 7 – 8.

The specification also describes that there is a tradeoff between the two fiber-forming materials that make up the two dissimilar yarns – one being lubricious, but

weak, the other being strong. The tradeoff is that the gains achieved in pliability and handleability by using the combination outweighs the loss of suture strength resulting from combining a weaker lubricious material with the stronger material. According to the specification, the resulting suture is one with improved handleability and pliability performance without significantly sacrificing its physical properties.

The '446 patent specifically refers to "pliability" in connection with "resistance to bending," (Ex. 3 at col. 1, ll. 11-15, l. 24) and "bending rigidity," (Ex. 3 at col. 6, ll. 44-45, col. 8, Table, ll. 44-46), which are the inverse of pliability.

One handleability characteristic specifically identified in the patent is "knot tie down." Ex. 3 at col. 6, ll. 7-8. Knot tie-down is a well-known suture handleability characteristic intended to be a measure, which can be either objective or subjective, of the ability of a knot formed in the suture to slide down the suture. Some other factors that can be measured which indirectly relate to knot tie-down include braid chatter (i.e., the smoothness of the braid) and the coefficient of friction (another objective measure of smoothness) of the braid surface.

With regard to knot tie-down, the specification states that while a coating can be added "*to further improve* the handleability and knot tiedown performance of the braid" (Ex. 3 at col. 6, ll. 5-8) [emphasis added], it also states that if the surface of the braid contains "a significant fraction of the lubricious yarn system, the . . . coating may be eliminated." Ex. 3 at col. 6, ll. 13-17. In other words, it is my opinion that the '446

patent is telling a person of ordinary skill in the art that the handleability (*e.g*, knot tie-down performance) is enhanced due to the braided construction of two dissimilar materials braided together, indeed improved so much in certain configurations that the need for coating can be eliminated.

In addition to pliability and knot tie-down, there are other suture handleability characteristics that were well known in the art at the time of the invention, and therefore, would be understood by a person of ordinary skill in the art to be included in improved handleability, as it is used in the '446 patent. They include tactile feel, compliance, tissue drag, knot security, knot stability, coefficient of friction, stiffness, softness, smoothness, lack of chatter, tissue abrasion and lie-down of the knot. The specification specifically or implicitly mentions some of these (e.g., knot security, knot stability, compliance, stiffness, coefficient of friction, lack of chatter). The others were well known in the suture art at the time of the invention and they were also recognized as such by Ethicon as well. I have reviewed Ethicon documents specifically mentioning these suture handleability characteristics, including documents during the development that lead to the '446 patent. Ex. 7. Mr. Jamiolkowski, one of the original inventors, also confirmed that suture handling properties includes knot tie-down, tactile feel (or hand), pliability, knot security and chatter. Ex. 8 at 140:5-24; 165:16-166:3. Dr. Steckel, another inventor, also confirmed that suture handling is "the ease of manipulation by the surgeon," with handling properties including "pliability, its roughness, smoothness,

and its frictional properties against itself," and also including chatter and knot tiedown. Ex. 6 at 77:3-78:2; 79:19-23.

The '446 patent describes the "physical properties" of the braid in terms of tensile strength and knot strength. Ex. 3 at col. 2. l. 66; col. 8, ll. 19-21, Table. Knot security is also mentioned as a property that is not sacrificed with improvements in pliability and handling properties. Ex. 3 at col. 2, ll. 66. Knot security provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking. Ex. 3 at col. 6, ll. 36-39.

I have reviewed Dr. Brookstein's report and I understand that he has been asked to assume that "the basic and novel characteristics [of the invention] are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid." Brookstein Report at 9.

I disagree with that assumption for the reasons stated above. In addition, Dr. Brookstein's report ignores much of what is taught in the specification. For example, while the specification does disclose direct intertwining contact between two dissimilar yarns, the '446 patent specification also discloses that the desired, novel result of this construction is a suture with better handleability and pliability performance without significantly sacrificing its physical properties. This is also consistent with Mr.

Jamiolkowski's statements. Ex. 8 at 163:11-20. Therefore, I believe Dr. Brookstein's assumption regarding the invention is inaccurate.

E. The coating added to Arthrex's FiberWire suture materially affects the pliability, handleability and physical properties of FiberWire

1. Coating materially affects suture handleability

It is my opinion that a person of ordinary skill in the art in February 1992 would understand the '446 patent to be teaching that coating materially affects suture handleability, including knot tiedown. For example, the '446 patent specification itself recognizes coating's effect on these properties where it states that coating the heterogeneous braid will "further improve the handleability and knot tiedown performance of the braid." Ex. 3 at col. 6, ll. 5-8.

Further, it was widely known and undisputed in the suture art in February 1992 that coating materially affects suture handling properties, including knot tie-down, and pliability. For example, there are many patents, including many Ethicon patents, that describe how coating affects these specific handling properties of suture. See, e.g., Ex. 9 at Abstract, col. 1, ll. 14-18; Ex. 10 at col. 1, ll. 11-15; Ex. 11 at col. 1, ll. 8-12; Ex. 12 at col. 1, ll. 12-15. There are also many articles on the subject as well. See, e.g., Ex. 13 at 525. I have also reviewed Ethicon documents stating the same thing. For example, in connection with the development of Ethicon's Panacryl suture, Ethicon stated that "the purpose of coating the Panacryl braided suture is to provide the suture with good

handling properties . . . such as knot slide, suture roughness, and knot security." Ex. 14 at 1.

This is also consistent with DePuy Mitek documents I have reviewed, all of which confirm that coating affects suture handling properties. Ex. 15 at 2. I have also reviewed Arthrex documents that also state that coating on the FiberWire product affects specific handling properties. For example, the directions for use (DFU) for FiberWire states that the coating acts as a lubricant for suture sliding, knot tying and ease of passing suture through tissue. Ex. 16. Dr. Steckel, one of the inventors of the '446 patent, also stated during his deposition that the reason why people coat sutures is to improve handleability and knot tie-down. Ex. 6 at 296:3-7.

It is also generally known in the suture art that coating materially affects a suture's tactile feel or smoothness. Ex 10 at col. 1. ll. 11-12. This is a subjective test usually performed by a surgeon in which the surgeon runs the suture through his hands and qualitatively evaluates its "feel." Sometimes, the surgeon attaches a quantitative value to the tactile feel of the suture so that it can be compared relative to other coated or uncoated sutures. I have reviewed Ethicon documents in which a tactile feel test is performed in evaluating different coating type and concentrations. Ex. 17 at Table 24.

Further, it is generally understood in the suture art that coating materially affects how easily a suture passes through tissue – commonly known as "tissue drag." The

effects of coating on tissue drag are described in Ethicon patents (Ex. 10 at col. 1, ll. 11-15) as well as other Ethicon documents. Ex. 18 at 11.

It was also generally understood in the suture art in February 1992 that coating materially affects suture pliability/bendability. It was known that adding coating to a suture could either improve pliability/bendability or adversely affect pliability/bendability. See Ex. 9 at col. 1, ll. 14-18; see also Ex 3 at col. 1, 20-22; col. 6, ll. 15-17.

I have also reviewed tests that show that the coating on FiberWire materially affects various handleability or pliability characteristics. In addition, I have reviewed results of a test entitled "Knot Tiedown" dated February 16, 2004 (Ex. 19). I understand the test was conducted by Arthrex and was intended to objectively show how coating affects knot tiedown.

The objective of the test was to simulate a surgeon's half-hitch knot and to determine the amount of force required to initiate movement of the knot down the line of suture – much like a surgeon moves the knot down the line of suture toward the wound. The test was conducted on both coated and uncoated samples of Arthrex's US No. 2 FiberWire suture. The test results for the two sutures were very different. By this test, Arthrex demonstrated that when coating is added to FiberWire suture, it becomes

approximately 2-1/2 times easier to slide the knot down the suture.[1] In my opinion, these results demonstrate that coating materially affects knot tiedown of FiberWire suture.

In addition to the above described test, I have suggested tests of my own on coated and uncoated samples of FiberWire suture. Like the Arthrex test, the tests I suggested were objective in nature and also demonstrate that coating materially affects the handleability or pliability characteristics of FiberWire suture. The tests were conducted by the Center for Tribology in Campbell, California ("CETR"). The results are attached as Ex. 20. I understand that many of the world's leading suture manufacturing companies – including Ethicon and U.S. Surgical Corp. – use CETR to conduct various tests on their own suture.

Specifically, the tests conclusively show that the knot tie-down, chatter, coefficient of friction, knot security, pliability and tissue drag characteristics of FiberWire are each materially affected by the addition of coating. For example, the knot tie-down (knot run-down) test measures the force required to initiate movement of a half-hitch knot formed on the suture and also the force required to slide the knot down the suture. The results of the knot tie-down test are a function of the smoothness of the surface of the braid. The results of the knot tie-down test performed by CETR

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[1] The mean peak force required to initiate slippage of the knot on the uncoated suture was 32.0N, whereas only 12.7N were required to initiate slippage of the knot on the coated suture.

demonstrate that approximately 1.8 times as much force was required to slide the knot on the uncoated FiberWire suture as compared with the coated FiberWire suture. Ex. 20 at 7-8.

The chatter and coefficient of friction tests are also measures of the smoothness of the braid surface and are also directly related to the knot tie-down test in that way. The more smooth the surface of the braid, the less force that is required to move the knot along the surface of the suture – this is a very desirable feature for surgeons working with surgical suture. Additionally, the more smooth the surface of the braid, the less chatter the knot will experience as it travels along the surface of the braid. The coating added to FiberWire smoothens out the "peaks" and "valleys" formed on the surface of the braid. As those peaks and valleys are smoothened, it becomes easier for the knot to move along the surface of the suture (i.e., less force is require to move the knot along the suture). The results of the coefficient of friction and chatter tests conducted by CETR are consistent with the knot tie-down test results. Specifically, the coefficient of friction for the uncoated FiberWire suture was approximately 1.8 times higher than that of the coated FiberWire suture. The chatter tests showed a similar differential between coated and uncoated FiberWire suture.

CETR's test results also show that the addition of coating to FiberWire suture improves the suture's pliability/bendability. Specifically, there was an approximately 63% difference in pliability/bendability for the coated and uncoated FiberWire samples,

demonstrating that the coating materially affects FiberWire's pliability/bendability. Ex. 20 at 3-4.

In addition, I conducted my own subjective "drape test" on samples of coated and uncoated FiberWire suture to determine the coating's effect on the pliability of the suture. The drape test involves draping the suture over my extended index finger and observing the degree to which the suture conforms to the shape of my finger. The results of my test showed that the coated FiberWire suture conformed to the shape of my index finger to a much greater degree than did the uncoated FiberWire suture, confirming that the coating materially affects FiberWire's pliability.

Further, Dr. Robert Burks performed a subjective tactile feel and knot tiedown analysis on coated and uncoated FiberWire suture. The results of his observations (Ex. 21) provide further support that the coating applied to FiberWire materially affects these handling properties. For example, Dr. Burks – not knowing which suture sample was coated and which was uncoated – consistently selected the coated sample as having better tactile feel as well as better tie-down performance.

Therefore, for the reasons explained above, it is my opinion the coating applied to the FiberWire suture materially affects the above-described handleability and pliability characteristics of FiberWire.

2. Coating materially affects FiberWire's knot security and knot strength

It is generally known in the suture art that coating materially affects a suture's knot security. See Ex. 22 at 211, 216; see also Ex. 13 at 528. Knot security is the measure of how many "throws" of a surgeon's knot are required to hold a knot secure. Generally speaking, the fewer the better. During a knot security test, a series of knots are thrown (i.e., formed and then slid down the suture to the desired location where they are tightened), then a pull test is conducted in which force is applied to the series of knots. If the suture breaks before the knot slips (i.e., loosens), then the suture has passed the test. If the knot slips before breaking, the suture fails.

I have reviewed patents that describe coating having both an adverse effect and a positive effect on suture knot security. See, e.g., Ex. 23, Ex. 24. The results appear to be dependent on the specific coating applied to the suture. In any event, the patents describe to a person of ordinary skill in the art that coating does materially affect knot security.

Furthermore, one of the tests that I suggested be performed by CETR conclusively demonstrates that coating does materially affect knot security of FiberWire. Specifically, much less force was required to undo the knot tied on the coated FiberWire as compared with the uncoated FiberWire, thus conclusively showing that the coating added to FiberWire materially affects its knot security. Ex. 20 at 5-7.

I have also reviewed knot strength test data captured by Pearsalls over a 4-1/2 year period which show that the addition of coating increases the knot strength of

FiberWire. Ex. 25. The data lists knot strength measurements of the heterogeneous braids used in Arthrex's FiberWire suture. The measurements were taken prior to and after coating. This is consistent with Ethicon documents I have reviewed which also describe an increase in knot strength after a coating has been applied to the suture. Ex. 14. Based on the test data I have reviewed, supported by Ethicon's documentation, it is my opinion that the coating applied to FiberWire materially affects knot strength of the suture.

3. Dr. Brookstein's Report

As explained above, I disagree with Dr. Brookstein's assumption that "the basic and novel characteristics [of the invention] are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid." Brookstein Report at 9. I also disagree with his conclusion that coating does not affect those basic and novel characteristics. While Dr. Brookstein states some conclusions (paragraph 36), he offers no technical evidence to support his conclusions.

Dr. Brookstein refers to Scanning Electron Micrographs and concluded that "the coating on the FiberWire suture does not substantially permeate the braided structure and does not reside between the braid yarns" and "that the coating only appears on the surface of the braid." Brookstein Report at ¶ 39.

Based on my review of the three micrographs, it appears that they are very different and that they are too unclear to draw any conclusions from them. Despite the lack of clarity, however, it appears that the individual braid filaments are grouped together to a much greater degree in the Tab G micrograph than they are in the Tab E micrograph. This is an indication that coating has permeated into the braid.

In any event, Dr. Brookstein's conclusions are inconsistent with the findings discussed below. In addition to the tests described above, CETR also conducted a scanning electron microscopy (SEM) examination of coated and uncoated FiberWire suture. My review of the scans performed to date appears to indicate that the coating does extend into the braid. Ex. 20 at Fig. 14. This is consistent with the effect coating has on FiberWire's pliability, as described above.

F. The nylon added to TigerWire suture materially affects its pliability

I understand that Arthrex's TigerWire suture has the same construction as FiberWire suture except that one of the PET carriers is replaced with nylon 6,6. All the reasons discussed in connection with FiberWire also apply to TigerWire. Further, it is well known in the art of manufacturing and/or processing of fibers that nylon 6,6 fibers of the type used in TigerWire are generally more stiff (i.e., less pliable) than fibers made of PET, as used in FiberWire and TigerWire. Ex. 26. Therefore, the act of removing one PET carrier and replacing it with a nylon 6,6 carrier during the braiding process, as is done with TigerWire, introduces a less pliable material into the composite braid.

It is also my understanding from discussions with Bill Benavitz of Arthrex that the diameter of the nylon 6,6 fibers used in TigerWire is greater than that of the PET which it replaces. Therefore, the nylon 6,6 fiber makes up a greater percentage of the braid cross-section area than does the PET fiber it replaces. Mr. Benavitz also informed me that Arthrex has received customer feedback that TigerWire is more stiff than FiberWire. In addition, I held a sample of both commercial FiberWire and TigerWire and the TigerWire felt stiffer and more course than the same sized FiberWire. I also conducted the drape test on the two samples and found that the FiberWire conformed to the shape of my finger to a much greater degree than the TigerWire, indicating that the addition of the nylon appears to make TigerWire stiffer and less pliable. For these reasons, it is my opinion that the addition of nylon 6,6 in TigerWire materially affects its pliability. Moreover, the course feel would suggest that the addition of the nylon would adversely affect knot tie-down.

Dr. Brookstein stated that the purpose of the nylon included in TigerWire is for visual identification, and refers to Peter Dreyfuss's testimony to support his opinion. Brookstein Report at ¶ 46. Whether or not Dr. Brookstein's report is accurate, it does not change the fact that, as explained above, the addition of nylon materially affects TigerWire's pliability.

G. Adding an adhesive to FiberStick suture materially affects its handleability

I understand that an adhesive material is applied to one end of Arthrex's FiberStick suture to stiffen a 12-inch length of the end of the suture. All the reasons discussed above in connection with FiberWire apply to FiberStick. In addition, based upon my review of Arthrex's marketing materials (Ex. 27), I understand that the stiffened portion materially improves the handleability of the suture in its intended application by easing passage of the suture through cannulated instruments and/or spinal needles. I also understand that the use of FiberStick also alleviates the need for monofilament or wire suture shuttles. Further, the stiffening of FiberStick restricts mobility between the fibers that make up the braid and also significantly restricts pliability/bendability of the suture. Therefore, it is my opinion that the addition of the adhesive to FiberStick materially affects the handleability of the suture.

H. The braids manufactured by Pearsalls are suitable for use in applications other than FiberWire sterilized surgical suture

The braids manufactured by Pearsalls for use in FiberWire are composed of UHMWPE and PET yarns braided together around a core of UHMWPE. The braids manufactured by Pearsalls are not sterilized, nor are they tipped. It is well known in the art of manufacturing and/or processing of fibers that the same construct of UHMWPE braided together with PET and surrounding a core of UHMWPE is also suitable for use as fishing line. For example, the Burgess application (Ex. 28) discloses a fishing line made of UHMWPE and polyester. Burgess also discloses that the braids may be coated – a process that is also performed by Pearsalls on the braids used for

FiberWire. I also understand that Pearsalls manufactures a fishing line known as Silkworm which has the same construction as the braids manufactured for FiberWire - UHMWPE and PET braided together around a core of UHMWPE. Ex. 29.

Further, the PTO examiner stated during prosecution of the application for the '446 patent that the heterogeneous braid invention was "an intermediate product [that] is useful to make other than the final product [of a surgical suture]," specifically stating that the heterogeneous braid invention was "deemed to be useful as a fishing line." Ex. 4 at 2. I agree. For these reasons, it is my opinion that the braids used for FiberWire are also suitable for use as fishing line, and I disagree with Dr. Brookstein's opinion that the braids of UHMWPE and PET manufactured by Pearsalls are not suitable for uses other than as FiberWire suture.

I. Arthrex's Marketing of FiberWire

Dr. Brookstein states that some of the benefits marketed by Arthrex in selling FiberWire (and TigerWire) are due to the invention claimed in the '446 patent. Brookstein Report at ¶ 73-77. I disagree with him for several reasons. For example, Arthrex's marketing of FiberWire heavily stresses the use of UHMWPE. Ex. 30 at 2. In particular, as a result of the use of UHMWPE, Arthrex's marketing materials state that FiberWire has "superior strength" and that "suture breakage during knot tying is virtually eliminated." Ex. 30 at 2. I also understand that both Mr. Sluss and Mr. Grafton stated during their depositions that the significant selling feature of FiberWire

is its strength. Ex. 31 at 22:10-23:5; Ex. 32 at 47:2-5. None of these important selling features of FiberWire are present in the '446 patent. In fact, the '446 patent concedes that some strength will be sacrificed in order to have a better handling suture.

Further, Arthrex touts "significant increases in . . . knot strength" (Ex. 30 at 2), whereas Ethicon's attorney stated that using UHMWPE in a suture application would result in "poor knot strength properties." Ex. 5 at 2-3. Arthrex also states that all of these advantages are achieved with much less elongation. Ex. 30 at 2. To the contrary, Ethicon's attorney pointed to the low elongation of UHMWPE as a key reason why it would not work for suture. Ex. 5 at 2-3.

Dr. Brookstein asserts that Arthrex "is highlighting the braiding of dissimilar materials as claimed" in the '446 patent and that "the braiding of polyethylene and PET in direct intertwining contact contributes to FiberWire's properties of strength and flexibility that Arthrex markets with respect to Ethibond." Brookstein Report at ¶¶ 76, 77. I disagree. As explained above, the superior aspects of FiberWire touted by Arthrex relate virtually exclusively to the increased strength from UHMWPE, a property that has nothing to do with the '446 patent.

J. Invalidity of claim 9 of the '446 patent

I have reviewed DePuy Mitek's Responses to Arthrex's Interrogatories and DePuy Mitek never indicated that it was asserting claim 9. I understand that claim 9

was asserted for the first time in this case in Dr. Brookstein's report. I did not include reasons in my first report why I believe claim 9 is invalid. I include them here.

I understand that claim 9 has all the limitations of claim 8 and adds some additional limitations. As I mentioned in my first report, it is my opinion that the combination of the '688 patent and the '802 patent discloses all of the structure of claim 8. As for claim 9, the '688 patent also describes that the ratio of fibers in the three sets can be 1:1:1 (Ex. 33 at col. 6, ll. 57-59), or 33.3% PP and 66.7% PET. PP is a first fiber-forming material within of the '446 patent and 33.3% is a volume fraction of the first fiber-forming material within the range of about 20-80%. Therefore, it is my opinion that the '688 patent discloses all of the additional subject matter of claim 9. The motivation to combine is the same as discussed in my previous report.

In the event the Court were to determine that "PE," as described and claimed in the '446 patent includes UHMWPE – then it is also my opinion that U.S. Patent No. 5,318,575 ("the '575 patent') discloses all of the subject matter of claim 9. For example, the '575 patent discloses a braid of one or more elongated filaments 26 of high molecular weight, high strength, where the remainder of the braid filaments 26 can be non-absorbable yarns. Ex. 34 at col. 4, ll. 8-24; FIG. 6. Therefore, the '575 patent discloses a volume fraction of the first fiber-forming material between about 20-80%.

Further, if the Court were to interpret "PE," of claim 1, to include UHMWPE, then it is my opinion that the combination of the Burgess application and i) the Cohan

article; ii) the DSM brochure; and/or iii) either one of the Harpell patents, would include every limitation of newly asserted claim 9 of the '446 patent. The motivation to combine these references is the same as the motivation I cited in my first report.

The Burgess application discloses a braided fishing line, "some braid filaments being of [UHMWPE] and other filaments being of polyester and/or nylon." Ex. 28 at 1. A person of ordinary skill in the art at the time of the invention of the '446 patent would understand that Burgess is suggesting a 50/50 mixture of the two materials, or something of that magnitude.

The disclosure of the Burgess application is also consistent with the construction of Silkworm fishing line as manufactured by Pearsalls. According to Pearsalls documents I reviewed (Ex. 29), the percentage of UHMWPE included in Silkworm fishing line is between approximately 50% and 77%.

Therefore, for these reasons, the Burgess application, combined with any of the other references described above, discloses every limitation of newly asserted claim 9.

VII. CONCLUSION

The opinions expressed in this report are based on the information currently available to me. I specifically reserve the right to formulate and offer additional opinions based on any other reports received from DePuy Mitek, or on any additional information that may be provided to me, and I likewise reserve the right to supplement

my opinions based on future court rulings, agreements between the parties, and additional evidence submitted by either party prior to or during trial.

Dated: March 24, 2006

Debi Prasad Mukherjee, Sc.D.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent Nos. 5,314,446 and other matters was served, via Fedex (Saturday delivery to Ms. Malinoski and regular delivery to Mr. Gleason), along with a courtesy copy of the text of this report (without exhibits), via email, on the following counsel for Plaintiff on the 24th day of March 2006:

Lynn A. Malinoski
Woodcock Washburn, LLP
One Liberty Place, 46th Floor
Philadelphia, PA. 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

Daniel J. Gleason
Nutter McClennan & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2604
Telephone: (617) 439-2000
Facsimile: (617) 310-9000

s/Salvatore P. Tamburo

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

Amended Supplemental Expert Report of Dr. David Brookstein

I. Background Information

1. Based on new information presented to me since my last report, I submit this supplemental report. Additional information that I have reviewed in forming my opinions is attached as Exhibit II.

II. Summary of Opinions

2. The samples tested by Dr. Gitis that he labeled "coated" and "uncoated" were manufactured differently. These manufacturing differences affect FiberWire's UHMWPE/PET braid. Therefore, it is my opinion that neither Dr. Gitis nor Dr. Mukherjee can make any scientifically reliable conclusions about the effect, if any, of FiberWire's coating based on Dr. Gitis' tests because they could not and did not determine what effects may be due to the coating and what effects may be due to the manufacturing differences between the samples (*e.g.*, the differences by which the UHMWPE/PET braids were made).

3. It is my opinion that Dr. Gitis' testing methodology was not based on accepted scientific methods or he failed to provide information that showed that his tests and analysis were based on accepted scientific methods. Therefore, it is my opinion that his tests and data cannot be relied on to analyze the effects, if any, of FiberWire's coating on the suture's properties.

4. It is my opinion that no reliable conclusions can be made about the effect, if any, of FiberWire's coating on the suture's properties based on Arthrex's knot tie-down test because either the "coated" or "uncoated" samples were manufactured differently or it is not known how they were manufactured.

III. Dr. Gitis' Tests Are Scientifically Unreliable Because The Tested Samples Differed In How They Were Manufactured

5. Dr. Gitis tested samples in which the only purported difference between the samples was that one set was "coated" and the other set was not. But the samples differed in more respects than just coating. Specifically, the "uncoated" sample was not heated and stretched, but the "coated" sample was heated and stretched twice, as is the case during the typical manufacturing of FiberWire sutures. Therefore, any conclusions that Dr. Mukherjee and Dr. Gitis made about the effect of a coating based on Dr. Gitis' tests are not reliable because they did not consider the whether the differences in properties, if any, were attributable to the stretching and/or heating.

6. My opinion is supported by the depositions of Mr. Hallett and Mr. Lewis in June 2006 and Pearsalls' manufacturing documents which show that the samples tested by Dr. Gitis were manufactured differently. I understand from counsel that Dr. Gitis tested FiberWire samples from Pearsalls batch 28893. Based on the deposition transcripts of Mr. Hallett and Mr. Lewis, I understand that the untreated FiberWire from batch 28893 that was used in Dr. Gitis' tests did not undergo the heating, stretching, and coating processes shown in Pearsalls' manufacturing flowchart (Ex. JJ) (Ex. KK, Lewis Dep. at 17:18-21; 18:15-17; 24:2-8). In this report, I refer to

the "uncoated" samples tested by Dr. Gitis as the untreated samples because this is a more accurate description. I also understand that the treated FiberWire sample that Dr. Gitis used did undergo the heating, stretching, and coating processes shown in Pearsalls' manufacturing flowchart (Ex. JJ) (Ex. KK, Lewis Dep. at 27:10-25; Ex. LL at PR08466). I refer to the "coated" samples tested by Dr. Gitis as the treated samples.

7. Based on my January 2006 inspection of Pearsalls' manufacturing operations and my review of their procedures, I understand Pearsalls' processes used to manufacture FiberWire. During the inspection of the Pearsalls' manufacturing facility, I personally witnessed the coating, heating, and stretching process used to make FiberWire. While at the inspection, I saw the stretching process. I saw exemplar pads that are tightened against the suture. The tightening of the pads against the suture provides a frictional force that must be overcome. This results in the suture being stretched as it is pulled at a rate of about 20 meters per minute. During my inspection, I plucked the FiberWire moving through the treating operations. Based on its resistance to transverse deformation, I observed that the FiberWire was under tension. I understand that Pearsalls refers to this manufacturing step as stretching (Ex. JJ; Ex. MM, Hallett Dep. at 32:12-14).

8. Based on my January 2006 inspection of Pearsalls' manufacturing operations and my review of their procedures, I understand Pearsalls' heat-treating process used to manufacture FiberWire. During my visit to Pearsalls' facility, I also saw the equipment that is used for the heat-treating operations. I learned that the FiberWire sutures are processed by traversing the suture through a hot-air, four-stage convection oven while under tension. The suture threadline speed through the oven is generally 20 meters/minute and each stage of the four-stage oven was about 2 meters in length (Ex. MM, Hallett Dep. at 110:18-21). Accordingly, the suture

threadline has a residence time in each zone equal to about 6 seconds. Zones 1 and 2 are heated with hot air at 100ºC (Ex. LL at PR8466). Zone 3 is heated with hot air at 130ºC, and zone 4 is heated with hot air at 170ºC (Ex. LL at PR8466). Thus, as the suture passes through the oven, the UHWMPE and PET braid is heated above 100°C but less than 170°C. The photographs that are attached to my expert report dated March 3, 2006 clearly show that the fibers have not fused or melted together.

9. It is my opinion that Pearsalls' heating and stretching processes affects FiberWire's properties. For example, it is my opinion that Pearsalls' heating and stretching processes will eliminate or reduce any minor bumps or irregularities along the suture surface, resulting in a smoother surface. This is described in the 446 Patent (Ex. D to my First Report at 5:61-6:1). Because heating and stretching affects surface properties, it affects the following suture properties: knot slippage, knot run-down, friction, chatter, and tissue drag. Since Dr. Gitis tested for these properties and Pearsalls' heating and stretching processes affect them, it is my opinion that any differences that he found cannot be attributed to only the coating on FiberWire. My opinion is supported by the testimony of Dr. Mukherjee who testified that hot stretching processes affect a suture's strength and handling properties (Ex. NN, Mukherjee Dep. at 106:18-109:5; 110:2-4). Also, Pearsalls' heating and stretching processes affect pliability because they affect the moment of inertia, the modulus of the fibers, and the fiber-to-fiber interaction. Since Dr. Gitis tested for pliability and Pearsalls' heating and stretching affects pliability, it is my opinion that any differences that he found cannot be attributed to only the coating on FiberWire.

10. Dr. Gitis tested untreated and treated FiberWire. As I understand his tests, he did not account for the stretching and heat-treating differences between the treated and untreated samples. Nor did Dr. Mukherjee account for these differences. Thus, they did not account for

whether the differences between the samples were due to differences between the heated and stretched UHMWPE/PET braid. Since the stretching and heat treating affects the properties for which Dr. Gitis was testing, it is not scientifically acceptable to attribute the differences in Dr. Gitis' results to only the coating on FiberWire.

IV. Dr. Gitis' Pliability Tests Are Scientifically Unreliable Because the Testing Methodology Is Either Flawed or Unexplained

A. Dr. Gitis' "Pliability" Test and Methodology Was Flawed

11. Dr. Gitis' "pliability" test is scientifically unacceptable because it is based on: (1) stiffness data determined by a test using non-uniform loading rates; (2) flawed diameter measurements; (3) flawed assumptions about the moment of inertia, as discussed in my previous report (and not repeated here); and (4) unexplained methodology for calculating "stiffness."

1. Dr. Gitis' Pliability Tests Are Scientifically Unacceptable Because They Used Non-Uniform Loading Rates

12. Dr. Gitis used a tensile test to measure a parameter that he used to determine pliability. As I described in my Rebuttal Expert Report, I do not believe that this is an accurate methodology for testing FiberWire's pliability. But even if it were to be used, the testing methodology would have to be reliable. Here, it was not.

13. There are two accepted ways to perform a tensile test. One is a constant rate of extension test. For this test, a tensile specimen is secured between two jaws; one is stationary, and the other extends at a constant rate with regard to time. A load cell is also connected linearly to one of the jaws. The load cell measures the tensile force in the specimen, as it is being extended. Thus, the test yields data for plotting force vs. extension, and from this data the specimen's force vs. elongation behavior can be determined. It is my experience that this tensile testing method is the most commonly used and accepted tensile test by those who regularly perform tensile tests

on linear structures such as sutures. This test is described in ASTM D2256-02 "Standard Test Method For Tensile Properties Of Yarns By The Single Strand Method" (Ex. OO).

14. The other accepted way to perform a tensile test is known as a constant rate of loading test. For this test, a tensile specimen is secured between two jaws with one being stationary and the other permitted to move such that the measured loads, which are also measured by a load cell, are increasing at a constant rate. This test is also described in ASTM D2256-02 "Standard Test Method For Tensile Properties Of Yarns By The Single Strand Method" (Ex. OO).

15. For the constant rate of loading test, the loading rate must be the same because it is well known that fibers, such as those used in FiberWire, are materials having time-dependent, visco-elastic behavior. For these types of materials, it is scientifically unreliable to draw any conclusions by comparing the stress-strain relationship of specimens with different loading rates.

16. Dr. Gitis states in his report that the "pliability" tests were conducted by the constant rate of loading method. In that regard, he states in his report that the force was "uniformly increasing at the rate of 0.33 kg./sec." I have examined the underlying data produced by Dr. Gitis and CETR. Based on my analysis of this data, the tests were not conducted as stated in Dr. Gitis' report. Dr. Gitis used different loading rates on each sample. I used the TRENDLINE function incorporated in MS Excel software, on the modulus data in the Excel file provided to me, to determine the loading rate for each sample and the regression factor (R^2, a measurement of the confidence between the actual data and curve or line which defines that data) and obtained the

following results:

	Treated Sample Loading Rate, kg/sec	R^2	Untreated Sample Loading Rate, kg/sec	R^2
1	0.094	0.9981	0.144	0.9984
2	0.060	0.9787	0.103	0.9931
3	0.074	0.9886	0.090	0.9947
4	0.050	0.9979	0.121	0.9988
5	0.036	0.9979	0.109	0.9968
6	0.073	0.9970	0.110	0.9890
7	0.053	0.9973	0.133	0.9905
8	0.058	0.9985	0.080	0.9925
Avg.	0.062		0.108	

As can be seen from this table, the load rates varied significantly between individual samples and even among the treated and untreated samples. In fact, the average loading rate for the untreated samples is approximately 75% greater than the average loading rate for the treated samples. Further, since the TRENDLINE function uses a linear relationship and the R^2 values are greater than the 95% accepted confidence level, the determined loading rates are accurate.

17. Consequently, no scientifically reliable "stiffness" conclusions can be drawn based on Dr. Gitis' tests because the loading rate for each of the individual samples was not the same. Neither Dr. Gitis nor Dr. Mukherjee accounted for the differences in loading rate. Therefore, any conclusions that they drew from this data and the "stiffness" values reported by Dr. Gitis are neither reliable nor comparable. In fact, Dr. Gitis testified that if the sample load rates were different, it would "jeopardize the results" (Ex. PP, Gitis Dep. at 163:17).

2. Dr. Gitis' Pliability Tests Are Scientifically Unreliable Because He Used the Wrong Diameter

18. In determining "stiffness," Dr. Gitis assumed a monofilament circular structure. He also determined stiffness based on the moment of inertia, which is a function of the diameter raised to

the fourth power for a circular monofilament.[1] As I discussed in my previous report, I disagree with this assumption, but assuming that it is correct, it is important to use the correct diameters. This is because any error in the diameter between the treated and untreated samples results in an error in the "stiffness" values calculated by Dr. Gitis. It is my opinion that Dr. Gitis did not use accurate diameter measurements, and therefore, Dr. Gitis' reported stiffness values are not scientifically acceptable.

19. I understand that Dr. Gitis used the same diameter for the treated and untreated FiberWire samples. That diameter was 0.65 mm (Gitis Report at 3). I understand from Dr. Gitis' deposition that CETR measured the samples' diameters with a caliper (Ex. PP, Gitis Dep. at 153:11-20). I am not able to fully review and analyze Dr. Gitis' diameter measurements because he did record these measurements or the testing methodology (Ex. PP, Gitis Dep. at 174:7-10).

20. It is my opinion that Dr. Gitis' measurements are inaccurate. Dr. Gitis' diameter measurements contradict the measurements taken by Pearsalls. I have reviewed PR08456-57 (Ex. QQ). These documents show that Pearsalls measured the treated FiberWire's average diameter as 0.586 mm and the untreated FiberWire's average diameter as 0.600 mm. Therefore, Dr. Gitis' measurements are different than Pearsalls' measurements. In fact, Pearsalls measured the maximum diameter of the treated suture as 0.599 mm and the maximum diameter of the untreated suture as 0.635 mm., which are both less than the 0.65 mm diameter used by Dr. Gitis.

21. It is my opinion that Pearsalls uses a more accurate methodology for measuring diameter than Dr. Gitis. I understand that Pearsalls measures the diameter according to its TM36 procedure (Ex. JJ; Ex. RR; Ex. SS; Ex. TT, Hallett Dep. at 40:8-42:4; Ex. MM, Hallett Dep. at

[1] Dr. Gitis' reported stiffness values also are dependent upon his assumption that the treated and untreated samples had a uniform circular cross-section. This not a correct assumption either.

174:12-20; 179:19-180:23; 185:4-9). Pearsalls' diameter measurement procedure (TM36) is stated to be performed according to the European pharamacopia (Ex. SS at PR8444). According to Pearsalls, the testing is accurate to 0.002 mm. (Ex. SS).

22. It is my opinion that Pearsalls' diameter measurement methodology is more accurate and scientifically reliable than using a caliper because it measures and keeps the transverse force constant. Dr. Gitis did not provide any information on whether he kept the transverse "crushing" force constant when he measured the sutures. Keeping the transverse "crushing" force constant is important because sutures are relatively compliant in transverse compression, indicating that they can deform during measurement and thereby yield inaccurate measurements. Because Dr. Gitis used a value (*i.e.*, 0.65 mm) that is higher than any valued measured by Pearsalls for the treated and untreated samples, obtained the same value for the treated and untreated samples, did not account for the "crushing" force, and used a caliper, it is my opinion that he did not use a scientifically reliable method for determining diameter.

3. The Stiffness Values Calculated By Dr. Gitis Were Not Performed With Scientifically Reliable Methods

23. Dr. Gitis purports to determine the stiffness values in Table 1 of his report by using the relationship between modulus of elasticity and moment of inertia. As I understand his methodology, Dr. Gitis determined the stiffness values according to the formula (slope/(3.14* D^2/4))* D^4/64. This is mathematically equivalent to (slope*D^2)/16. He used a diameter of 0.65 mm, and the slope was purportedly determined from the data he obtained from his tests.

24. His calculations are based on the determination of the slope of the force v. strain curves. I tried to reproduce his calculations but was not able to obtain the same results that he lists in Table 1. Dr. Gitis did not state in his report how he calculated the slope.

At deposition, Dr. Gitis testified that he calculated the slope of the curves by taking the change in force after the preload was set to the completion of the test, and divided that by the strain between after the preload was applied and the end of the test (Ex. PP, Gitis Dep. at 187:8-15). Although this is not a scientifically acceptable methodology, it will work if the data is a straight line or the best fit through the data is essentially linear. My review of the data indicates that it essentially follows a straight line relationship. Thus, I determined the slope and the stiffness values as Dr. Gitis states that he did, but I did not generate the same stiffness values (Ex. UU). This means that Dr. Gitis did not determine slope as he stated in his deposition. I do not know what methodology he used to determine slope.

25. I also tried to determine Dr. Gitis' stiffness values by fitting a best straight line through the data following the pre-load and determining the slope of that curve. This is a scientifically acceptable method for determining slope. I used the TRENDLINE function, which produces a linear regression analysis, incorporated in MS Excel software to determine the slope of each data set and the R^2 factor derived from each of the 16 sutures. I then multiplied each of the slope values by the diameter squared and divided it by 16, as Dr. Gitis suggested (Ex. PP, Gitis Dep. at 186:7-11).

The following table represents the pliability or stiffness for each of the 16 tested sutures using this method for determining slope.

	Treated, kg*m^2	R^2	Untreated, kg*m^2	R^2
1	8.71E-07	0.9974	7.50E-07	0.9936
2	3.74E-07	0.9883	7.23E-07	0.9983
3	6.17E-07	0.9936	9.17E-07	0.9980
4	3.58E-07	0.9915	7.49E-07	0.9955
5	2.81E-07	0.9904	5.35E-07	0.9831
6	4.28E-07	0.9891	1.00E-06	0.9766
7	3.99E-07	0.9984	1.04E-06	0.9958
8	3.40E-07	0.9906	8.24E-07	0.9976
Avg.	4.59E-07		8.18E-07	

As can be seen from this table, these pliability values are different than the ones reported in Dr. Gitis' report. Therefore, I do not understand what methodology Dr. Gitis used for determining slope and the "stiffness" values in Table 1 of his report. Because he has not shown what methodology he used, his methodology cannot be said to be scientifically acceptable.

26. I also note that Dr. Gitis' "pliability" test data details a parameter called "ZABS." I do not know what this parameter means, and Dr. Gitis was unable to explain what it means (Ex. PP, Gitis Dep. at 143:7-13). Thus, depending on what the parameter means, it may further affect my opinions.

B. No Reliable Conclusions About Pliability Can Be Drawn From Dr. Gitis' "Pliability" Test Because The Results Are Contradicted By Dr. Gitis' Tissue Drag Test

27. If the pliability test performed by Dr. Gitis is assumed to be reliable (it is my opinion that it is not) and the tissue drag test performed by Dr. Gitis is also assumed to be reliable (it is my opinion that it is not as described below), the "pliability" results from each test should be consistent. It is my opinion that the "pliability" results from each of these tests is not consistent and therefore no reliable conclusions about pliability can be drawn from Dr. Gitis' tests, even if

they were assumed to be proper tests. My analysis below assumes that the tissue drag test is a proper and reliable test. But it is not because the samples have differences other than coating, it incorrectly assumes a monofilament structure, it incorrectly assumes a circular cross section, it incorrectly assumes a constant diameter for all samples, and it assumes that the tissue-drag tests were done properly, which they were not.

28. The tissue drag test is described on page 12 of the CETR report. In the report, it is stated that a 20 mm length of suture was extended at a constant rate of 1 mm/sec while continuously recording the pulling force. Prior to the suture slipping, the test is similar to that specified in ASTM D2256-02 "Standard test method for tensile properties of yarn by the single strand method." Thus, putting aside the incorrect assumptions inherent in Dr. Gitis' tests and the flaws in the tissue drag tests (see below), prior to slipping between the leather pads, the recorded data can be used to determine the force/elongation relationship of the tested specimens.

29. I examined the data before slippage between the leather pads from the time period 0.1 to 0.5 seconds. This was to ensure that the time period of collected data was the same for each suture.

30. After examining the data, I plotted the individual force vs. strain data relationship for each of the eight coated and eight uncoated sutures. These plots are attached to this report as Ex. VV. I then used the TRENDLINE function incorporated in MS Excel software to determine the slope of each curve derived from each of the 16 sutures. These slopes represent the force on the thread line at a given time, or stated another way, force per unit time. Dr. Gitis reported that the specimens were originally 20 mm and the jaw moved at a constant rate of 1 mm/sec. Accordingly, the strain rate on the specimen was 0.05 (mm/mm)/sec. I then divided the slope of each curve by 0.05/sec (the strain rate) and the assumed cross sectional area of each suture

(based on Dr. Gitis' assumed 0.65 mm) to obtain the tensile modulus. I then multiplied this value by the moment of inertia, based on Dr. Gitis' incorrect assumptions, to obtain the "pliability or stiffness" data for each suture. The following table represents the pliability or stiffness data for each of the 16 samples from the tissue drag test.

Specimen	Untreated, kg* m^2	R^2	Treated, kg* m^2	R^2
1	4.10E-07	0.9966	7.07E-07	0.9990
2	4.07E-07	0.9967	4.98E-07	0.9935
3	3.87E-07	0.9949	3.74E-07	0.9939
4	3.45E-07	0.9945	7.82E-07	0.9949
5	3.46E-07	0.9944	7.03E-07	0.9549
6	3.08E-07	0.9918	3.07E-07	0.9852
7	4.37E-07	0.9947	4.39E-07	0.9949
8	3.71E-07	0.9945	4.85E-07	0.9921
Avg.	3.76E-07		5.37E-07	

31. Based on this analysis, the tissue drag tests shows that the stiffness of the untreated suture was less than the stiffness of the treated suture. This contradicts what Dr. Gitis reported for his "pliability" test in Table 1 of his report where he reports that that the stiffness of the untreated suture was higher than the treated suture. Thus, even assuming his tests were done properly, no reliable conclusions can be drawn from them because the data from the tissue drag test contradicts the data from the "pliability" test.

V. Dr. Gitis' Knot Slippage Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained

32. It is my opinion that Dr. Gitis did not determine the knot slippage strength using a scientifically reliable testing methodology. According to Dr. Gitis report, his methodology is described on page 5 of his report. He states that the parallel rods were pulled apart at a constant velocity of 1 mm/sec. While the rods were pulled, CETR personnel measured and recorded the force until either the knot untied or 3 mm of slippage occurred. However, the tests were not conducted as stated in his report.

33. I examined the underlying data of the knot slippage test and Dr. Gitis' deposition testimony. According to Dr. Gitis, the Z column in the knot slippage data is the vertical displacement of rods (Ex. PP, Gitis Dep. at 230:12-14). Consequently, if the test was performed at a constant velocity as stated in the test report, the Z value should increase 1 mm every second. However, the data does not show this. In fact, the data shows that the displacement decreases with increasing time. At deposition, Dr. Gitis testified that the data was not consistent with a constant velocity of 1 mm/sec. (Ex. PP, Gitis Dep. at 246:9-12). Further, Dr. Gitis was not able to explain why the data showed that the Z value decreased (Ex. PP, Gitis Dep. at 245:13-19). Also, he could not fully explain what the data in the F_X and F_y columns represented (Ex. PP, Gitis Dep. at 229:16-20). Therefore, the test was not performed as reported, and the data is not explained. Based on the information provided, the testing methodology is not a scientifically acceptable test because there is no adequate explanation of the test methods or the data. Absent a complete explanation of how the test was conducted, Dr. Gitis' knot slippage strength values are just data without meaning and context, and they cannot be scientifically relied upon.

VI. Dr. Gitis' Knot Run-Down Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained

34. It is my opinion that Dr. Gitis did not determine the knot run-down using a scientifically reliable test methodology. His methodology is partially described on page 7 of his report. However at deposition, Dr. Gitis could not fully describe the test methodology for this test. He testified that he did not know: (i) how the suture was attached to the upper brass rod (Ex. PP, Gitis Dep. at 236:3-9); and (ii) what he did with the lower end of the suture (Ex. PP, Gitis Dep. at 236:23-237:1). Dr. Gitis stated that he didn't remember how the test was conducted (Ex. PP, Gitis Dep. at 237:8-12). Thus, based on the information provided, the test, as described, is not a scientifically acceptable test because there is no adequate explanation of the test methods or how

the data was obtained. Absent a complete explanation of how the test was conducted, Dr. Gitis' knot run-down values are just data without meaning and context, and they cannot be scientifically relied upon.

35. Although Dr. Gitis' knot-run down data is unreliable, even if were to be relied upon, it is inconclusive. Dr. Gitis' test results show in Table 3 that two of the treated samples had the same knot-run down force as two of the untreated samples. If coating has a materially affect on knot run-down, then I do not understand why on two occasions the untreated samples had the same knot run-down force as two of the treated samples. Neither Dr. Gitis nor Dr. Mukherjee was able to explain this (Ex. PP, Gitis Dep. at 218-226; Ex. WW, Mukherjee Dep. at 451:3-12). Absent an explanation, it is my further opinion that it is not scientifically reliable to conclude from the data that coating causes a smaller knot run-down force.

36. Also, I do not fully understand Dr. Gitis' knot run-down data because he could not explain it. He did not know what the data in the F_f column represented (Ex. PP, Gitis Dep. 241:10-11), and how the tests were conducted. Thus, I do not fully understand Dr. Gitis' data and tests because he could not explain the data.

37. Further, I do not understand Dr. Gitis' methodology for reporting his data because the data he generated does not appear to correspond to the reported values in Table 3. For example, Dr. Gitis' data shows that coated sample 7 appeared to have the highest knot run-down peak force (Ex. XX, coated sample 7 denoted by blue unfilled circles). Yet, his reported data in Table 3 differs because coated sample 7 had a value of 0.19 kg., which was not the highest value reported in the chart. Dr. Gitis was not able to explain this difference (Ex. PP, Gitis Dep. at 242:16-243:4). Thus, I do not understand what methodology Dr. Gitis used, and his unknown methodology cannot be considered reliable.

VII. Dr. Gitis' Friction Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained

38. Dr. Gitis' friction tests are scientifically unreliable because the testing methodology was flawed, and there was no explanation of how the coefficient of friction was determined. Dr. Gitis' report partially describes the friction tests on page 9. According to Dr. Gitis, two sutures were each held in a suture holder by clamping one suture end and holding the other suture end by tightening a screw against the suture (Ex. PP, Gitis Dep. at 249:4-21). Dr. Gitis did not measure the clamping force (Ex. PP, Gitis Dep. at 249:22-24). Further, he did not measure the torque on the screw or the force placed on the suture by the screw (Ex. PP, Gitis Dep. at 249:25-250:2). Nor did he accurately control how tight the screw was placed against the suture (Ex. PP, Gitis Dep. at 250:16-252:9). Because Dr. Gitis' friction tests relies on rubbing two sutures against each other, the tension under which the sutures are subject to in the holder affects the measured friction parameters. Because Dr. Gitis did not use a scientifically reliable method to check the tension on the sutures in the suture holders, no scientific reliable conclusions can be drawn based on his friction tests.

39. Based on the information that was provided, Dr. Gitis' friction test methodology is also not scientifically reliable because he could not explain how his testing machine and software determined the coefficient of friction (Ex. PP, Gitis Dep. at 261:10-14; 263:14-265:6). Absent an explanation of how the friction coefficients were determined, they are values without any meaning, and they cannot be scientifically relied upon to determine the coefficient of friction.

40. Also, I do not fully understand Dr. Gitis' friction data because he could not explain it. He did not know what the F_f represented (Ex. PP, Gitis Dep. at 261:1-9). Thus, I do not fully understand Dr. Gitis' data and tests because he could not explain the data.

VIII. Dr. Gitis' Chatter Data Is Unreliable Because the Testing Methodology Is Not Known

41. It is my opinion that Dr. Gitis' chatter data on page 11 of his report is not scientifically reliable because no explanation was provided as to how it was determined. Dr. Gitis provides a brief explanation on page 11 of his report but does not explain specifically how it was determined (*i.e*. he does not explain what "maximum and minimum" amplitudes were used and how they were used to generate the results from the friction and knot run-down tests). At his deposition, he was not able to explain how the chatter values were determined (Ex. PP, Gitis Dep. at 268:1-269:5). Therefore, absent an explanation of how the chatter values were determined, they are just values without any meaning, and they cannot be scientifically relied upon to draw conclusions.

42. Also, it appears that certain data related to Dr. Gitis' chatter determinations were not maintained by Dr. Gitis (Ex. PP, Gitis Dep. at 267:10-23). Since I did not have the opportunity to review the data, I cannot use it to understand whether Dr. Gitis used a scientifically acceptable method.

43. Further, Dr. Gitis' tests also show that one of the treated samples had about the same chatter value (0.012) as at least four of the untreated samples (0.013, 0.013, 0.012, 0.011), and another of the treated samples (0.010) had a value that was the same as at least one of the untreated samples (0.011). If coating had a material effect on chatter, then I do not understand why some of the untreated samples had the same chatter value as some of the treated samples. Neither Dr. Gitis nor Dr. Mukherjee was able to explain this discrepancy (Ex. PP, Gitis Dep. at 269:22-270:2; Ex. WW, Mukherjee Dep. at 464:21-465:4). Based on these results, it is my further opinion that it is not scientifically reliable to conclude from the data that coating materially affects FiberWire's chatter.

IX. Dr. Gitis' Tissue Drag Data Is Unreliable Because the Testing Methodology Is Flawed

44. Dr. Gitis' tissue drag test involved dragging a suture through two pieces of leather that were clamped together. The results of the tissue drag test are a function of how tight the leather was clamped against the suture. If the force applied to the suture by the leather differed between samples, this will lead to different results that cannot be compared. Dr. Gitis clamped the leather together with a nut and bolt (Ex. PP, Gitis Dep. at 272:24-273:1). But Dr. Gitis did not control the force that was applied to the leather or how tightly the sutures were clamped between the leather (Ex. PP, Gitis Dep. at 273:2-5). Thus, because Dr. Gitis did not control the clamping force, he did not use a scientifically reliable methodology for performing the tissue-drag test, and it is not scientifically acceptable to compare the data he obtained between samples.

45. I also note that Dr. Gitis states in his report at page 12 that he conducted a second different tissue drag test with a needle. He did not provide any data or results from this test in his report or subsequent to his report. I understand that he no longer has the data (Ex. PP, Gitis Dep. at 271:10-272:9). Thus, I have not been provided the opportunity to assess this test or its results. It could be that this test contradicts his other tests, but I do not know because I have not seen the data.

46. Also, I note that Dr. Gitis' tissue drag data does not seem to correlate with his reported data. For example, his data shows that untreated sample 5 (magenta) had the highest static tissue-drag force (Ex. YY). But his report in table 6 shows that the highest static tissue-drag force for the untreated samples was sample no. 4. Dr. Gitis was not able to explain this discrepancy (Ex. PP, Gitis Dep. at 279:11-280:5). Thus, it is not clear what methodology Dr. Gitis used to obtain his reported tissue drag values. Therefore, for this additional reason, his unknown methodology cannot be considered scientifically reliable.

X. Arthrex's Knot-Down Test Is Scientifically Unreliable For Assessing The Effects of FiberWire's Coating on FiberWire's Properties

47. Dr. Mukherjee also relies on a "knot-tie down" test performed by Arthrex (Ex. 19 to Dr. Mukherjee's Responsive Report, see Mukherjee's Responsive Report at 24-25), which purportedly shows the effects of FiberWire's coating on knot tie-down properties. I am not aware of any documentation that establishes the construction and manufacturing processes that were used to construct the "uncoated" suture used in this test. Therefore, absent information about the construction and manufacturing of the tested samples, it is not possible to say that the only difference between the samples was coating. Further, it is scientifically unreliable to attribute the differences in the test results to coating.

48. I understand that Arthrex's counsel has indicated that the samples produced as ARM 25452 (DM Ex. 430) may be uncoated sutures from the same batch as that used in Arthrex's knot tie-down test. The sample designated as ARM25452 is white and does not have FiberWire's blue dye. I note that Mr. Grafton's email from July 2004 indicates that the "uncoated" samples used in Arthrex's knot-run down test were "removed from production before dying and coating" (Ex. ZZ). The sample and Mr. Grafton's email suggest that the untreated samples used in Arthrex's knot tie down test was not dyed, scoured, coated, stretched, or heated. Therefore, even if the sample known as ARM 25452 is the type that was tested by Arthrex, there is no scientific reliable method for making any conclusions about the materiality of the affects of FiberWire's coating on FiberWire's properties.

XI. The FiberWire Photos Provided in Dr. Gitis' Report Do Not Show Coating

49. Based on the information provided about the pictures shown in Dr. Gitis' report it, I cannot determine whether they show any coating. My opinion is supported by Dr. Gitis who stated that he could not see coating when he observed the samples under magnification (Ex. PP,

Gitis Dep. at 285:9-14). I understand that Dr. Mukherjee has opined that Figure 14 in Dr. Gitis' report shows coated sutures because the fibers are allegedly spaced closer together (Ex. WW, Mukherjee Dep. at 461:23-462:10). It is my opinion that this is not a scientifically acceptable analysis or conclusion. I understand from Dr. Gitis' and Dr. Mukherjee's testimony that it is not known what part of FiberWire is shown in the photos, and it is not known how exactly the material shown was handled (Ex. WW, Mukherjee Dep. at 462:12-18; Ex. PP, Gitis Dep. at 289:8-16). Thus, the spacing between the fibers could be a function of how the sutures were handled, cut, or clamped during the photos, as described by Dr. Gitis (Ex. PP, Gitis Dep. at 288:12-20). There is no reliable methodology provided by Dr. Mukherjee for opining that Figure 14 shows coating. I note that Dr. Gitis had other pictures taken but did not provide them for analysis (Ex. PP, Gitis Dep. at 286:7-17).

XII. Dr. Burks' Testimony Supports My Opinion that the Effects of FiberWire's Coating Are Not Material

50. I have reviewed Dr. Burks' testimony and deposition transcript. I understand that he considered the differences between the treated and untreated sutures as "subtle" and "pretty close" (Ex. AAA, Burks' Dep. at 87:7-13; 88:1-3; 96:18-19; 98:19-25). He also stated that he could not "clearly feel a difference" (Ex. AAA, Burks Dep. at 88:9-10). This supports my opinion that any purported differences are not material.

51. Also, Dr. Burks testified that wearing gloves would make a difference in whether he, as a very experienced surgeon, can even tell the difference between the treated and untreated samples (Ex. AAA, Burks Dep. at 96:24-97:5; 72:1-73:6). In fact, he testified that he may not have been able to tell a difference if he used just gloves (Ex. AAA, Burks Dep. at 73:9-14; *see also* 96:24-97:5). He testified that using gloves made a difference in the feel of a suture (Ex. AAA, Burks. Dep. at 72:7-8). I understand from Dr. Burks that he wears gloves when using FiberWire in

surgery (Ex. AAA, Burks Dep. at 51:12-14). Thus, Dr. Burks' testimony regarding the use of gloves supports my opinion that the differences between the treated and untreated sutures are not material.

Dated: July 24, 2006

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

CERTIFICATE OF SERVICE

I certify that the foregoing Amended Supplemental Expert Report of Dr. David Brookstein was served in the manner indicated below on July 24, 2006 on the following:

Via e-mail without exhibits and
via Federal Express delivery (without exhibits)
Charles W. Saber
Dickstein Shapiro LLP
1825 Eye Street NW
Washington D.C. 20006-5403
saberc@dsmo.com

Via Federal Express
Christopher Weld, Jr.
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109

Dated: July 24, 2006

Erich M. Falke

Amended List of Additional Materials Considered

Deposition Transcript of Mr. Lewis with exhibits
Deposition Transcript of Mr. Hallet from June 30, 2006 with exhibits
Steven B. Warner, *Fiber Science* 1995
Deposition Transcript of Dr. Gitis with exhibits
Deposition Transcript of Dr. Mukherjee with exhibits
CETR Testing data
Pearsalls documents 008433-008473
CETR documents0001-79
FiberWire Samples Ex. 388, 390, 438, 429, 389, 428, 235, 236, 237
Dr. Burks Transcript with exhibits
"An Experimental Method for Determining the heat Transfer Coefficient of Polymeric Fibers and Yarns During Rapid Convective heating" by R. Brooks published in The Journal of the Textile Institute 1984, No. 6, I then pp. 398-404.
DM. Ex 430
DM. Ex. 433
DM. Ex. 434
ARM25591
PR08325-08382
TestWorks®4 "Continuing to set the standard for material, component, and subassembly testing software"
Gordon Laboratory Seminar Series Lent 2006
ASTM International, Designation: D 638-03, "Standard Test Method for Tensile Properties of Plastics"

-----Original Message-----
From: Tamburo, Salvatore [mailto:TamburoS@dicksteinshapiro.com]
Sent: Monday, July 24, 2006 6:17 PM
To: Malinoski, Lynn A. (Woodcock Washburn); Bonella, Michael J. (Woodcock Washburn)
Cc: Saber, Charles
Subject: Dr. Gitis

Lynn and Mike:

Recently, it has come to our attention that Dr. Gitis's testing lab, CETR, was infiltrated by a software virus around the same time Dr. Gitis was conducting his tests of coated v. uncoated FiberWire and preparing his expert report based on those tests. Dr. Gitis conducted an investigation and has reason to believe that the actual test results included in his report may be based upon data that was corrupted due to the virus; however, Dr. Gitis cannot be certain whether the corruption occurred at the time the data was collected or when the report was generated. Dr. Gitis will be repeating his tests on additional samples of coated and uncoated FiberWire suture and preparing a new expert report. We plan to serve his new expert report as soon as possible and certainly within the next few weeks. After that, Dr. Gitis will be available for deposition with regard to his new expert report. We, of course, will afford Dr. Brookstein the opportunity to make further comments on Dr. Gitis's new report.

Regards,
- Sal

Sal Tamburo
Dickstein Shapiro LLP
1825 Eye Street NW | Washington, DC 20006
Tel (202) 420-5164 | Fax (202) 420-2201
tamburos@dicksteinshapiro.com

WOODCOCK WASHBURN
INTELLECTUAL PROPERTY LAW
ATLANTA • PHILADELPHIA • SEATTLE

PHILADELPHIA OFFICE
One Liberty Place, 46th Floor
Philadelphia, PA 19103
215.568.3100
Fax: 215.568.3439

July 25, 2006

MICHAEL J. BONELLA
PHILADELPHIA OFFICE
215-564-8987
bonella@woodcock.com

Via Hand Delivery & Facsimile
Salvatore Tamburo, Esq.
Dickstein Shapiro Morin &
Oshinsky LLP
2101 L Street, N.W.
Washington, D.C. 20037

Re: DePuy Mitek, Inc. v. Arthrex, Inc. & Pearsalls, Inc.
Case No. 04-12457 PBS

Dear Sal:

Your July 24th allegations of an alleged virus, coming immediately after Dr. Brookstein's supplemental report was served, are surprising. They are further surprising because the produced CETR data do not appear to be corrupt at all.

Mitek does not agree that Dr. Gitis can supplement his report, create new reports, or conduct more testing. As an initial matter, regardless of any alleged "virus," Dr. Gitis' tests were not properly conducted, he did not test the correct samples, he did not know how the tests were conducted, he did not check the accuracy of his report when he wrote it, and he destroyed test data. Further, both Dr. Gitis and Dr. Mukhurjee admitted that neither of them were experts in interpreting the results of Dr. Gitis' tests. None of those issues relate to any so-called virus. Thus, regardless of any alleged virus, there is no legitimate reason for Dr. Gitis to conduct new tests, and Mitek will move to oppose any efforts by Dr. Gitis to supplement his report or to conduct tests.

Your correspondence states that Dr. Gitis report "may be based upon data that was corrupted" and he cannot be certain when the alleged corruption occurred. An allegation that his report "may" be based on corrupt data is not a reason for Dr. Gitis to reconduct his tests, much less to fix his many errors that have nothing whatsoever to do with any alleged virus. Notably, your correspondence does not provide any detail regarding the alleged virust/corruption or explain precisely how it allegedly affected the data in Dr. Gitis' report. Please provide more detail regarding the virus/corruption, produce the corrupt data, identify the alleged virus by name, identify the specific machines it allegedly infected, explain precisely what data are

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allegedly corrupt and how it affected Dr. Gitis' report, and provide all information in Dr. Gitis' and CETR's possession regarding this alleged virus, including any action taken by third-parties to address the virus.

If Dr. Gitis' report is based on corrupt data, Mitek expects that Arthrex will prove that to be the case, including the exact extent of the alleged corruption and when it occurred. If Arthrex and Pearsalls insist on this course of action and are permitted to do so by the Court, Mitek will conduct a full forensic investigation of Dr. Gitis' machines and computer systems with forensic and virus experts regarding this alleged virus. In the meantime, please immediately sequester the allegedly infected computers/machines, and other electronic records of this alleged virus and how it affected Dr. Gitis' work, so that Mitek can have forensic/virus experts analyze them, if that becomes necessary. Please confirm immediately that this has been done.

Sincerely,

Michael J. Bonella

-----Original Message-----
From: Saber, Charles [mailto:SaberC@dicksteinshapiro.com]
Sent: Tuesday, August 01, 2006 4:09 PM
To: Malinoski, Lynn A. (Woodcock Washburn); Bonella, Michael J. (Woodcock Washburn)
Cc: Tamburo, Salvatore
Subject: DePuy Mitek v. Arthrex

Lynn and Mike:

We just received word today that Dr. Gitis has an emergency that caused him to leave the country immediately for approximately three weeks. It appears that Dr. Gitis's absence will cause a delay in the testing, although we are trying to check to see if any delay can be avoided or lessened.

We will keep you advised of any further information that we receive.

Chuck

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INTELLECTUAL PROPERTY LAW
ATLANTA • PHILADELPHIA • SEATTLE

PHILADELPHIA OFFICE
One Liberty Place, 46th Floor
Philadelphia, PA 19103
215-568-3100
Fax: 215-568-3439

ERICH M. FALKE
215-557-5926
falke@woodcock.com

March 28, 2006

Charles Saber, Esquire
Dickstein Shapiro Morin & Oshinsky LLP
2101 L Street, N.W.
Washington, D.C. 20037

Re: DePuy Mitek, Inc. v. Arthrex, Inc.
Case No. 04-12457 PBS

Dear Chuck:

We received the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters" ("the Report"). Unfortunately, there are many issues that need to be resolved before Mitek's experts can fully respond to the Report. Please produce the following information by this Friday (March 31), so that Mitek's experts can evaluate this information in advance of April 7th:

(1) a sample of suitable length of each of the coated and uncoated sutures (as sterilized by Sterile Systems) referenced in Section 3 of Ex. 20 of the Report;

(2) documents and communications between the Center for Tribology, Inc. ("CETR") and (i) Arthrex; (ii) Dr. Mukherjee; or (iii) Dickstein Shapiro Morin & Oshinsky concerning any aspect of Ex. 20 to the Report, including, but not limited to, documents concerning the "suggestions of the law firm" as noted on p. 2 of Ex. 20 of the Report;

(3) Arthrex's and Dr. Mukherjee's documents concerning CETR including, but not limited to, all documents showing the relationship between them;

(4) CETR documents that relate to this case including, communications, documents related to any testing performed, any tests and test results not reported, documents describing the testing protocols;

(5) documents and files from Dr. Norm Gitis, Mr. Michael Vinogradov, Sterile Systems, AMER (including, but not limited to, Tony Lin) that relate to this case;

(6) documents that describe the samples tested including Arthrex and Pearsalls documentation (*e.g.*, "DT sheets," manufacturing specifications, invoices, purchase orders);

(7) a copy of each of the references listed on page 17 of Ex. 20 of the Report; and

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(8) documents sufficient to describe the sterilization specifications used to sterilize the suture samples.

Also, please advise whether your firm represents any of the following entities or people and if so, when they are available for deposition. Mitek's expert cannot fully respond to Dr. Mukherjee's report without the benefit of these depositions.

(1) The person from Pearsalls who manufactured the samples, took them from the manufacturing line, and sent them to Arthrex.

(2) The person who ordered the samples from Pearsalls.

(3) Each CETR person involved in designing and performing tests outlined in Ex. 20 of the Report.

(4) Each person that handled the tested sutures at Sterile Systems and performed the sterilization.

(5) Each person that handled the tested sutures from AMER and each person from AMER who performed work related to this case.

As Mitek will not be able to take depositions before April 7th, Mitek's experts can only respond on April 7th based on the information that is available to them. If Arthrex will not provide this information, please explain Arthrex's reasons for not providing it. If formal subpoenas are needed, please advise. Also, please be advised that there may be other information that Mitek's experts will need.

Additionally, Mitek believes Arthrex improperly marked Ex. 20 of the Report as "Confidential: Non-Patent Prosecution Counsel Only." Please provide your reasons for marking it with such a designation.

Sincerely,

Erich M. Falke

EMF/td

WOODCOCK WASHBURN
INTELLECTUAL PROPERTY LAW
ATLANTA • PHILADELPHIA • SEATTLE

PHILADELPHIA OFFICE
One Liberty Place, 46th Floor
Philadelphia, PA 19103
215-568-3100
Fax: 215-568-3439

ERICH M. FALKE
215-557-5926
falke@woodcock.com

March 30, 2006

Charles Saber, Esquire
Dickstein Shapiro Morin & Oshinsky LLP
2101 L Street, N.W.
Washington, D.C. 20037

Re: DePuy Mitek, Inc. v. Arthrex, Inc.
Case No. 04-12457 PBS

Dear Chuck:

Please let me know if we will be receiving, by March 31, the information requested in my March 28 letter so that our expert can potentially respond by the April 7 deadline.

Sincerely,

Erich M. Falke

EMF/td

WOODCOCK WASHBURN
INTELLECTUAL PROPERTY LAW
ATLANTA • PHILADELPHIA • SEATTLE

PHILADELPHIA OFFICE
One Liberty Place, 46th Floor
Philadelphia, PA 19103
215-568-3100
Fax: 215-568-3439

ERICH M. FALKE
215-557-5926
falke@woodcock.com

April 4, 2006

Charles Saber, Esquire
Dickstein Shapiro Morin & Oshinsky LLP
2101 L Street, N.W.
Washington, D.C. 20037

Re: DePuy Mitek, Inc. v. Arthrex, Inc.
Case No. 04-12457 PBS

Dear Chuck:

This letter confirms our telephone discussion of Friday, March 31 in which we discussed my March 28th, 30th, and March 31st letters.

You represented that no untested CETR suture samples exist, other than 2 cm, which you explained was insufficient for testing. You also stated that you were not aware of whether any of the samples tested by CETR exist. But you represented that you would follow up with CETR and provide us with any existing samples. Please let us know immediately if any samples exist. If samples exist, please produce them immediately with information sufficient to describe whether they are tested or untested samples and the samples' origin. If no samples exist, please explain what CETR did with the tested and untested suture samples.

We discussed the documents that we had requested. You represented that you are checking to determine whether documents exist in the following areas:

> documents between CETR and (i) Arthrex; (ii) Dr. Mukherjee; or (iii) Dickstein Shapiro Morin & Oshinsky concerning any aspect of Ex. 20 to the Report, including, but not limited to, documents concerning the "suggestions of the law firm" as noted on p. 2 of Ex. 20 of the Report;
>
> CETR documents that relate to this case including, communications, documents related to any testing performed, any test results or test data (including data recorded by machine or humans, and data not reported by CETR) and detailed testing procedures;
>
> documents that describe the samples tested including Arthrex and Pearsalls documentation of the samples (*e.g.*, "DT sheets," manufacturing specifications, invoices, purchase orders);

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documents sufficient to describe the sterilization specifications used to sterilize the suture samples; and

documents describing the origin and explanation of the samples produced after the close of fact discovery on about February 7, 2006.

Also, you represented that you are "considering" whether to provide us with the requested deposition of the Pearsalls employee who took the samples from the manufacturing line. As we explained, that deposition is necessary so that Mitek can understand exactly what sutures were tested by CETR. Mitek is entitled to this information, and we urge you to provide it. We requested a response by today at the latest. You have not responded.

Also, we sent you a letter describing certain unproduced Pearsalls' batch records referenced in Ex. 25 to Dr. Mukherjee's Responsive Report. When we spoke on Friday, you were not prepared to discuss this issue. We are still awaiting a response on this issue.

Mitek's experts cannot fully respond to Dr. Mukherjee's report without the benefit of this information. It is almost the close of business on Tuesday, leaving just 3 days before Mitek's experts are due to file their rebuttal reports, and you have not afforded them the opportunity to review the requested information. You ignored our letters of last week until Friday afternoon, and we still have not heard from you with respect to whether we will be receiving any of the requested information. Consequently, Mitek reserves the right to supplement its reports after it receives this information. We also reserve the right to seek the other information requested in our letters regarding Arthrex's expert reports.

Sincerely,

Erich M. Falke

EMF/td

WOODCOCK WASHBURN
INTELLECTUAL PROPERTY LAW
ATLANTA • PHILADELPHIA • SEATTLE

PHILADELPHIA OFFICE
One Liberty Place, 46th Floor
Philadelphia, PA 19103
215-568-3100
Fax: 215-568-3439

ERICH M. FALKE
215-557-5926
falke@woodcock.com

April 10, 2006

Charles Saber, Esquire
Dickstein Shapiro Morin & Oshinsky LLP
2101 L Street, N.W.
Washington, D.C. 20037

Re: DePuy Mitek, Inc. v. Arthrex, Inc.
Case No. 04-12457 PBS

Dear Chuck:

I am writing in response to your Friday evening email. You claim not to have been delaying in responding to our requests for discovery concerning Arthrex's and Pearsalls' rebuttal expert reports. But you have not responded to any of our discovery requests regarding Dr. Mukherjee's Responsive and Dr. Gitis' expert reports. You claim to be trying to determine what has been requested. But you have not raised any questions about the requests since we spoke on March 31, 2006. Further, your alleged confusion is really silly because the requests are pretty basic (e.g., all data generated during all tests, samples of what was tested, detailed testing procedures, communications among CETR and Dr. Mukherjee, and your firm, sterilization procedures, documents describing the tested samples and their chain of custody, documents or witnesses who can identify the samples produced after close of fact discovery).

Also, you have failed to advise whether you will be making fact witnesses available to testify regarding the samples which were made for CETR. As we have expressed on numerous occasions, Mitek wants to depose the Pearsalls fact witness, who has first hand knowledge of the identify of the tested samples, including their construction, what processing they underwent, and how they were handled.

Further, we want to depose the fact witness from the sterilization lab regarding the sterilization processes and the handling of the tested samples and the lab that took pictures of the samples. As we indicated, these depositions were not as high a priority given the limited time to prepare rebuttal reports.

It does not take any research to let us know whether you will be making fact witnesses available for deposition. We asked that you let us know about the Pearsalls fact witness by early last week, so that we could take that deposition before the responsive expert reports were served. We have not received a response. Please advise whether we should resolve the issues with respect to fact witnesses and documents by motions.

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At this point, you have not afforded Mitek's experts the opportunity of reviewing the requested information before preparing their rebuttal reports. We will be supplementing them once the requested information is produced and/or moving to exclude portions of Arthrex's and Pearsalls' expert reports.

Sincerely,

Erich M. Falke

EMF/td

WOODCOCK WASHBURN
INTELLECTUAL PROPERTY LAW
ATLANTA • PHILADELPHIA • SEATTLE

PHILADELPHIA OFFICE
One Liberty Place, 46th Floor
Philadelphia, PA 19103
215-568-3100
Fax: 215-568-3439

ERICH M. FALKE
215-557-5926
falke@woodcock.com

April 13, 2006

Charles Saber, Esquire
Dickstein Shapiro Morin & Oshinsky LLP
2101 L Street, N.W.
Washington, D.C. 20037

Re: DePuy Mitek, Inc. v. Arthrex, Inc.
Case No. 04-12457 PBS

Dear Chuck:

You have not responded to any of our requests for discovery concerning Dr. Mukherjee's and Dr. Gitis' reports. We first made a request for certain information on March 28, 2006. It is now April 13th, the due date for rebuttal expert reports, and we have not received any of the requested information. Nor have you even indicated if Arthrex and Pearsalls will be producing the requested information.

On April 7, 2006, you claimed not to be "delaying," but we have not heard from you since that communication. Based on your lack of response since March 28, 2006, we understand that Arthrex and Pearsalls will not be producing the requested information. You appear to be engaging in the classic lawyer "I don't understand what you want" delay/obstruction tactic when the requests are straightforward. We discussed the requests on March 31, 2006, and you have not indicated any "confusion" since then. We will be addressing the issue by motion.

Sincerely,

Erich M. Falke

EMF/td

WOODCOCK WASHBURN
INTELLECTUAL PROPERTY LAW
ATLANTA • PHILADELPHIA • SEATTLE

PHILADELPHIA OFFICE
One Liberty Place, 46th Floor
Philadelphia, PA 19103
215-568-3100
Fax: 215-568-3439

May 31, 2006

MICHAEL J. BONELLA
PHILADELPHIA OFFICE
215-564-8987
bonella@woodcock.com

Via Email
Salvatroe Tamburo, Esq.
Dickstein Shapiro Morin &
Oshinsky LLP
2101 L Street, N.W.
Washington, D.C. 20037

Re: DePuy Mitek, Inc. v. Arthrex, Inc. & Pearsalls, Inc.
Case No. 04-12457 PBS

Dear Sal:

Thank you for your May 26, 2006 communication expert deposition scheduling. It appears that we have agreed on the following schedule (except Mr. O'Donnell), please confirm.

Deponent	Date/Location
Dr. Burks	6/7 Salt Lake City, Utah
Dr. Gering	6/7 Phil.
Dr. Mukherjee	6/13 D.C.
Dr. Bosco	6/15 D.C.
Mr. Witherspoon	6/20 D.C.
Dr. Gitis	6/21 D.C.
Dr. Hermes	6/27 Phil.
Mr. O'Donnell	6/16 or 6/19 Phil.
Pearsalls	6/30 U.K.

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Pearsalls' Depositions

It is not clear whether the four fact witnesses that you have identified can authenticate and explain which manufacturing processes Pearsalls used to make the coated and uncoated samples that were tested by Dr. Gitis. We are requesting that Pearsalls produce fact witnesses that have first-hand knowledge of the processes that were used to make the specific samples that Dr. Gitis, Dr. Mukherjee, and Dr. Burks tested. We also believe that both Pearsalls & Arthrex have an obligation under Rule 26 to identify such witnesses.

Unfortunately, in advance of the depositions, we cannot commit to a time limit on the Pearsalls' depositions. But we will make every effort to keep them as brief as possible. Although it is possible that we may not need to depose all four witnesses, it is also possible that we may need to depose all of them. Again, while we make every effort to be as brief as possible and to limit who is deposed, we ask that you hold availability on July 1 (or start on 6/29), so that we can ensure that we can complete the depositions. Hopefully, that will not be necessary, but we want to make sure that there is sufficient time to complete the depositions.

We understand that Pearsalls & Arthrex refuse to answer the interrogatories. But if they do so, we may be able to shorten and avoid unnecessary depositions.

Are the witnesses available to be deposed in London? Also, please confirm the dates this week, so that we can book the airline tickets, which are somewhat limited.

Also, we have repeatedly requested documents that appear to be relevant to these depositions, such as the Pearsalls batch records for batch 28893, but we have not received them.

Dr. Gitis' Samples

We are still requesting the entirety of what remains of what Dr. Gitis actually tested. We would like the samples now, so that our expert can consider them in preparing his supplemental report, and we can consider them before we depose Dr. Gitis. If you do not produce them until the deposition, it hinders our ability to ask questions at the deposition, which might result from an analysis of the samples. We would rather have the samples now, so that we can avoid any issue of having to reconvene the deposition to address issues raised by Mitek's experts' analysis of the samples after the deposition.

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Dr. Brookstein's Deposition & Report

We agree in principal to the dates that you have proposed with respect to Dr. Brookstein, but propose a slight adjustment in your proposed dates because there is not sufficient time for Dr. Brookstein to complete his report and the Markman hearing in the SlingShot case may be scheduled for July 6th. We propose that he serves his supplemental report on July 13th (this assumes that the Markman in the SlingShot case is moved) and is deposed on July 25th. We do, however, reserve the right to reconsider these dates if we have not received the requested information by then and/or there is not sufficient time for his to complete his analysis based on information that was requested, but not produced.

You raise the issue of why Dr. Brooskstein will be supplementing his report. I do not wish to engage in an argument with you about this, but rather am just responding to your question. He will be supplementing based on a variety of information that was requested, but not produced before his rebuttal report was served. This includes but is not limited to Dr. Gitis' data, Pearsalls' documents, Dr. Gitis' documents, Pearsalls' depositions, and samples. Also, we still do not fully understand the tests that Dr. Gitis conducted (which is the reason for the repeated requests regarding procedures and equipment used by Dr. Gitis), so he will be supplementing based on his deposition and those documents (if they are produced). We disagree that Dr. Gitis' report explains his tests sufficiently so that they can be fully understood or replicated. That is why we have been requesting documents concerning the general machines and procedures that he used since March.

Sincerely,

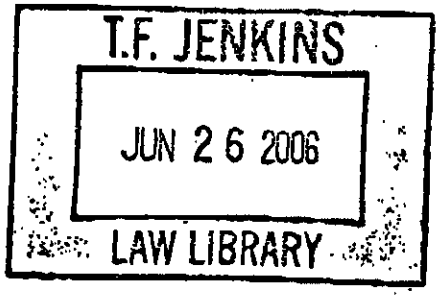
Michael J. Bonella

MOORE'S FEDERAL PRACTICE
THIRD EDITION

VOLUME 6

JAMES WM. MOORE

2006



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Editorial Offices
744 Broad Street, Newark, NJ 07102 (973) 820-2000
201 Mission St., San Francisco, CA 94105-1831 (415) 908-3200
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MATTHEW BENDER

(Rel.150-6/06 Pub.410)

[2]—Supplementation Duty Extends to Expert Witness Disclosures

The duty to supplement or correct disclosures extends to the testimony of an expert from whom a disclosure report is required (*see* § 26.23[2]),[15] even though Rule 26(e) generally applies to written discovery rather than deposition testimony. This duty applies to the information contained in the report as well as to the expert's deposition testimony.[16] It is not unusual for an expert to change opinions in preparation for and even during trial.[17] However, the last minute appearance of a new expert witness or the expansion of previously disclosed expert testimony often has the effect of undermining the adversary's trial preparations.[18]

A party may not use a supplemental report to disclose information that should have been disclosed in the initial expert report, thereby circumventing the requirement for a timely and complete expert witness report.[18.1]

Any additions or other changes with regard to the expert witness information must be disclosed by the time the party's pretrial disclosures are due under Rule 26(a)(3);[19] that is, at least 30 days before trial, unless otherwise directed by the court (*see* § 26.24).[20] As noted by one commentator, the pretrial disclosures

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[15] *See* Fed. R. Civ. P. 26(a)(2)(B).

[16] *See* Fed. R. Civ. P. 26(e) advisory committee's note (1993) (reproduced verbatim at § 26App.09[2]).

[17] **Change in opinion from pretrial litigation.** *See* Newell Puerto Rico, Ltd. v. Rubbermaid Inc., 20 F.3d 15, 21, 22 (1st Cir. 1994) (testimony of expert was admissible despite contention that expert's testimony differed from opinions rendered during pretrial litigation).

[18] **Preparation of witnesses.** *See* Williams v. Monarch Mach. Tool Co., 26 F.3d 228, 231 (1st Cir. 1994) (one-week delay in trial granted so that adverse party may prepare its own expert witness for new line of questions and rebuttal).

[18.1] **Supplementation cannot be used to correct major omission in initial report.** *See* Keener v. United States, 181 F.R.D. 639, 642 (D. Mont. 1998) (court concluded that "supplemental" report was so substantially different from initial report that it fell outside any reasonable notion of correcting incomplete or inaccurate expert report, as contemplated by rule requiring supplementation).

9th Circuit — *See* Keener v. United States, 181 F.R.D. 639, 642 (D. Mont. 1998) (court concluded that "supplemental" report was so substantially different from initial report that it fell outside any reasonable notion of correcting incomplete or inaccurate expert report, as contemplated by rule requiring supplementation).

11th Circuit — *See* Reid v. Lockheed Martin Aeronautics Co., 205 F.R.D. 655, 662 (N.D. Ga. 2001) (plaintiff was not permitted to file "supplemental" expert witness reports, which substantially revised analysis in original reports and revised deposition testimony, after court-imposed deadline for expert witness reports and information).

[19] *See* Fed. R. Civ. P. 26(e)(1).

[20] Fed. R. Civ. P. 26(a)(3).

required by Rule 26(a)(3) are usually otherwise directed by the court, because they are contained in the court's pretrial order. Consequently, any supplementation of expert witness information should take place on or before the date of the pretrial order.[21]

[3]—Supplementation and Correction Is Continuing Duty

The duty to supplement and correct disclosures and responses is a continuing duty and no motion to compel further supplementation is required.[22] Supplementation should not be confused with motions to compel for incomplete discovery responses.[23] The duty to supplement responses is continuing. For example, if after answering interrogatories, additional information becomes known to the answering party, this information must be disclosed and no additional interrogatories are necessary to obtain this information.[24]

The duty to supplement does not depend on repeated requests by an adversary for updated information. The fact that a party's attorney does not know about the updated information is irrelevant; the duty exists nevertheless.[25]

The duty to amend is not limited to circumstances in which the failure to amend constitutes a knowing concealment.[26] Rather, the duty to supplement and correct

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[21] Joseph, *Emerging Expert Issues Under the 1993 Disclosure Amendments to the Federal Rules of Civil Procedure,* 164 F.R.D. 97, 112 (1996); *see* Reid v. Lockheed Martin Aeronautics Co., 205 F.R.D. 655, 662 (N.D. Ga. 2001) (although Rule 26(e)(1) requires parties to supplement incorrect or incomplete information "at least" 30 days before trial, it "does not bestow on litigants unfettered freedom to rely on supplements produced after a court-imposed deadline")

[22] **Continuing duty.** *See* Alldread v. City of Grenada, 988 F.2d 1425, 1436 (5th Cir. 1993) (motion to compel need not precede court's imposition of sanction for failure to supplement expert interrogatory response).

[23] **Distinction between Rule 26(e) and Rule 37(a).** Alldread v. City of Grenada, 988 F.2d 1425, 1436 (5th Cir. 1993) (motion to compel required for sanctions under Fed. R. Civ. P. 37(a) for failure to produce but not under Fed. R. Civ. P. 26(e) for failure to supplement); *see also* Broadcast Music, Inc. v. Xanthas, 855 F.2d 233, 238 (5th Cir. 1988) (sanctions may be imposed under Fed. R. Civ. P. 37(b) for failure to produce documents only when court has entered order compelling discovery).

[24] **Duty to supplement interrogatory responses.** *See* Pasant v. Jackson Nat'l Life Ins. Co., 137 F.R.D. 255, 257 (N.D. Ill. 1991) (plaintiff had continuing obligation to supplement answers to interrogatories).

[25] **Repeated requests unnecessary.** *See* Arthur v. Atkinson Freight Lines Corp., 164 F.R.D. 19, 20 (S.D.N.Y. 1995) (nondisclosure of personal injury plaintiff's medical records unjustified).

[26] **Knowing concealment.** Fed. R. Civ. P. 26(e)(2). Prior to the 1993 amendments, parties were required to amend seasonably discovery responses on learning that the response was no longer true and the circumstances were such that the failure to amend the response was a knowing concealment. A prior response only had to be supplemented if the circumstances made failing to amend a "knowing concealment." *See* Fortino v. Quasar Co., 950 F.2d 389, 396 (7th Cir. 1991) (applying "knowing concealment" standard under pre-1993 law).

LEXSEE 2006 US DIST LEXIS 28263

SAINT-GOBAIN CORPORATION, Plaintiff/Counterclaim defendant, v GEMTRON CORPORATION, Defendant/Counterclaim plaintiff.

Case No. 1:04-cv-387

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MICHIGAN, SOUTHERN DIVISION

2006 U.S. Dist. LEXIS 28263

May 9, 2006, Decided

SUBSEQUENT HISTORY: Motion granted by *Saint-Gobain Corp. v. Gemtron Corp., 2006 U.S. Dist. LEXIS 28268 (W.D. Mich., May 9, 2006)*

PRIOR HISTORY: *St.-Gobain Corp. v. Gemtron Corp., 2006 U.S. Dist. LEXIS 27864 (W.D. Mich., May 9, 2006)*

COUNSEL: [*1] For Saint-Gobain Corporation, plaintiff: Barry J. Herman, Arthur Irwin Neustadt, Jean-Paul Phillipe Marie Lavalleye, Michael E. McCabe, Jr., Oblon Spivak McClelland Maier & Neustadt PC, Alexandria, VA; Mark S. Pendery, Rhoades McKee, Grand Rapids, MI.

For Gemtron Corporation, defendant: Randall G. Litton, Eugene J. Rath, III, Matthew Gipson, Price Heneveld Cooper Dewitt & Litton, Grand Rapids, MI; Stanley Allen Schlitter, Mark P. Vrla, Marshall J. Schmitt, Paul David Margolis, Jenner & Block LLP, Chicago, IL.

For Facilitative Mediator, mediator: William W. Jack, Jr., Smith Haughey Rice & Roegge, PC, Grand Rapids, MI.

For Gemtron Corporation, counter-claimant: Stanley Allen Schlitter, Mark P. Vrla, Marshall J. Schmitt, Paul David Margolis, Jenner & Block LLP, Chicago, IL; Eugene J. Rath, III, Matthew Gipson, Price Heneveld Cooper Dewitt & Litton, Grand Rapids, MI.

For Saint-Gobain Corporation, counter-defendant: Arthur Irwin Neustadt, Jean-Paul Phillipe Marie Lavalleye, Oblon Spivak McClelland Maier & Neustadt PC, Alexandria, VA; Mark S. Pendery, Rhoades McKee, Grand Rapids, MI.

JUDGES: Wendell A. Miles, Senior U.S. District Judge.

OPINIONBY: Wendell A. Miles

OPINION:

ORDER ON [*2] SAINT-GOBAIN'S MOTION TO STRIKE THE APRIL 10, 2006 TAYLOR SUPPLEMENTAL EXPERT REPORT

Presently before the court is Plaintiff/Counterclaim defendant Saint-Gobain's Motion to Strike the April 10, 2006 Taylor Supplemental Expert Report (docket no. 270). Defendant/counterclaim plaintiff Gemtron has opposed the motion. For the reasons to follow, the court **GRANTS** the motion.

Discussion

Paul Taylor is Gemtron's damages expert. Saint-Gobain seeks to have Mr. Taylor's most recent "supplemental" expert report (titled "Second Supplemental Expert Report of Paul H. Taylor, April 10, 2006") excluded because the report was not provided at least 90 days before trial as required by *Fed.R.Civ.P. 26(a)(2)(C)*. Saint-Gobain also argues that Mr. Taylor's most recent report contains substantially increased figures for both lost profits and reasonable royalties and that Gemtron has not offered a justifiable excuse for submitting a new report so close to the trial date.

Fed.R.Civ.P. 26(a)(2)(C) requires expert reports to be disclosed "at least 90 days before the trial date or the date the case is to be ready for trial" "[i]n the absence of other directions from the court or stipulation [*3] by the parties[.]" *Fed.R.Civ.P. 37(c)(1)* provides that

> A party that without substantial justification fails to disclose information required by *Rule 26(a)* or *26(e)(1)*, or to amend a prior response to discovery as required by *Rule 26(e)(2)*, is not, unless such failure is

> harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed. In addition to or in lieu of this sanction, the court, on motion and after affording an opportunity to be heard, may impose other appropriate sanctions. . . .

Gemtron does not dispute that it did not provide Mr. Taylor's most recent report at least 90 days before trial. However, Gemtron argues that there were reasons for the belated disclosure, namely that Mr. Taylor had requested more information, Saint-Gobain also wanted this documenting information, and the parties had agreed that Saint-Gobain could depose Mr. Taylor as well as present its own rebuttal expert. (Apparently, Saint-Gobain has decided not to call the rebuttal expert, Rodney Crawford, who is not listed in the final pretrial order.)

The issue could be viewed as simply one of supplementation of expert disclosures as [*4] contemplated in *Fed.R.Civ.P. 26(e)(1)*, which in turn incorporates *Rule 26(a)(3)*, which requires disclosure at least 30 days before trial unless otherwise directed by the court. However, the court is not persuaded that Mr. Taylor's most recent report falls within boundaries of supplementation provided by *Rule 26(e)(1)*. Review of Mr. Taylor's earlier report, dated December 22, 2005, indicates that he reached a specific conclusion regarding Gemtron's lost profits which did not include lost unit sales of tempered glass because he had requested additional financial information *from Gemtron* which not yet been provided by the company for reasons having nothing to do with Saint-Gobain. Therefore, if his analysis was incomplete, it was incomplete because Gemtron did not provide its own expert with enough of its own financial information and not because of a lack of information from Saint-Gobain.

In addition, regarding reasonable royalty damages, Mr. Taylor's earlier report stated that he had "concluded to rely on the RoyaltySource and Licensing Economics Review data indicating industry and guideline patent(s) median royalty rates of approximately 5.0% of sales." Mr. Taylor does not in [*5] that earlier report state in any way that his analysis of a reasonable royalty was incomplete. To allow Gemtron to seek a change in its expert's conclusions based solely on information, such as licensing agreements, pursued by Saint-Gobain would defeat the purpose of disclosure because it would permit the bolstering of a report based solely on a desire to answer the opposing party's anticipated challenges. This would effectively amount to unlimited expert opinion preparation. See *Akeva LLC v. Mizuno Corp., 212 F.R.D. 306, 310 (M.D.N.C.2002)* ("The Court cannot accept a definition of supplementation which would essentially allow for unlimited bolstering of expert opinions. *Rule 26(e)* envisions supplementation when a party's discovery disclosures happen to be defective in some way so that the disclosure was incorrect or incomplete and, therefore, misleading. . . . It does not cover failures of omission because the expert did an inadequate or incomplete preparation. . . . To construe supplementation to apply whenever a party wants to bolster or submit additional expert opinions would reek havoc in docket control and amount to unlimited expert opinion preparation"); [*6] see also *Sharpe v. United States, 230 F.R.D. 452, 462-463 (E.D. Va. 2005)* (plaintiff not permitted to supplement expert reports in order to remedy incomplete review performed by experts). The obligation to supplement does not grant a party a right to ignore court deadlines, reopen discovery, find "new facts," generate new expert reports, and then claim different damages. *DAG Ent., Inc. v. Exxon Mobil Corp., 226 F.R.D. 95, 110 (D.D.C. 2005)*.

Gemtron argues that Saint-Gobain is not prejudiced by the belated "supplementation" of Mr. Taylor's report. However, as noted above, Mr. Taylor's most recent report substantially increases his earlier damage calculations. These increased figures establish that Saint-Gobain is indeed prejudiced by the belated disclosure.

Finally, as for Gemtron's argument that the parties had an agreement regarding expert discovery, Gemtron has not shown that the parties had an agreement that Gemtron could supplement its expert report after December 22, 2005. The evidence provided by Gemtron suggesting an agreement between the parties indicates that counsel for Saint-Gobain anticipated that Mr. Taylor would be deposed "after supplemental [*7] damages reports are exchanged." However, the e-mail documenting this agreement is dated November 1, 2005, several weeks before the date of Mr. Taylor's December 22, 2005 supplemental report; the e-mail does not imply that Saint-Gobain was agreeing to yet further supplementation after December, 2005. In addition, although Gemtron has submitted the affidavit of its counsel who states that Saint-Gobain's counsel said the parties "previously had agreed that Saint-Gobain's damages expert, Rodney L. Crawford, would be allowed to submit an expert report two weeks after [Taylor] was to be deposed[,]" this does not indicate an agreement on Saint-Gobain's part that it would not oppose amendment of Mr. Taylor's report. Gemtron has therefore not shown that Saint-Gobain agreed to a waive the 90-day disclosure requirement.

Conclusion

For the foregoing reasons, the court GRANTS Saint-Gobain's motion. The April 10, 2006 Second Supplemental Expert Report of Paul Taylor is stricken and shall not be used as evidence at trial. n1

n1 By way of a footnote in its response brief, Gemtron argues that "Mr. Taylor's report *will need to be supplemented at least one more time* to account for damages arising from the new shelves [recently added to the claims of infringement]" (emphasis supplied). It is noted that Gemtron has not requested permission to supplement Mr. Taylor's report yet again, and the current ruling is by no means intended to suggest that the court would permit one or more additional amendments to the report of Gemtron's damages expert.

[*8]

So ordered this 9th day of May, 2006.

Wendell A. Miles

Senior U.S. District Judge

LEXSEE 2001 U.S. DIST. LEXIS 12211

CHARLES D. STEIN v. FOAMEX INTERNATIONAL, INC., et al.

CIVIL ACTION No. 00-2356

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

2001 U.S. Dist. LEXIS 12211

August 15, 2001, Filed

DISPOSITION: [*1] Defendants' Motion to Preclude GRANTED. Defendants' Motion to Strike GRANTED.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff property owner filed suit against defendant lessors alleging violations of several environmental statutes. The lessors subsequently moved for partial summary judgment. The lessors asserted that the property owner's expert filed an affidavit that clearly contradicted the opinions expressed in his expert report. The lessors therefore filed the instant motions to strike and to preclude.

OVERVIEW: The property owner contended that the lessors contaminated the property and he alleged violations under several federal environmental statutes. The property owner hired an environmental investigator who because the property owner's expert in the litigation. The lessors believed that the expert's affidavit contradicted his expert report and deposition testimony, and was filed only to allow the property owner to survive the motion for partial summary judgment. The court held that because the affidavit was filed after the date set for the serving of expert reports, the affidavit did not qualify as an original expert report. Also, the affidavit was not considered to be a supplement to the expert report where the changes were not made in accordance with Fed. R. Civ. P. 26. The court held that preclusion of the evidence was appropriate because the affidavit was filed in bad faith and the lessors were prejudiced by its late filing.

OUTCOME: The lessors' motions to preclude and to strike were granted.

LexisNexis(R) Headnotes

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN1] Fed. R. Civ. P. 26 requires that parties disclose the identity of any expert witness who may be used at trial. Fed. R. Civ. P. 26(a)(2)(A). That disclosure must also be accompanied by a written report prepared and signed by the witness. Fed. R. Civ. P. 26(a)(2)(B). The expert report shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor, as well as the data or other information considered by the witness in forming the opinions. Assuming the court establishes a schedule for such disclosures, parties must disclose their expert reports at the times and in the sequences directed by the court. Fed. R. Civ. P. 26(a)(2)(C).

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN2] Fed. R. Civ. P. 26 imposes a duty to supplement expert reports.

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN3] See Fed. R. Civ. P. 26(e)(1).

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN4] Any additions or changes to the information contained in an expert report shall be disclosed by the time

the parties disclosures under Fed. R. Civ. P. 26(a)(3) are due. Disclosures pursuant to Fed. R. Civ. P. 26(a)(3) shall be made, unless otherwise directed by the court, at least 30 days before trial. Fed. R. Civ. P. 26 (a)(3).

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
Civil Procedure > Discovery > Misconduct
[HN5] Failure to properly disclose or supplement information in accordance with Fed. R. Civ. P. 26 can result in sanctions pursuant to Fed. R. Civ. P. 37(c)(1). Fed. R. Civ. P. 37 provides that a party that without substantial justification fails to disclose information required by Fed. R. Civ. P. 26(a) or Fed. R. Civ. P. 26(e)(1) is not, unless such failure is harmless, permitted to use as evidence at a trial any witness or information not so disclosed. Fed. R. Civ. P. 37 provides for other sanctions as well, and the determination of which sanction to impose is within the sound discretion of the trial court.

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
Civil Procedure > Discovery > Misconduct
[HN6] Discretion notwithstanding, the exclusion of critical evidence is an extreme sanction. Indeed, the United States Court of Appeals for the Third Circuit requires more than a literal violation of Fed. R. Civ. P. 26; before a court preludes a party from presenting certain evidence at trial, it must first find that the party: (1) revealed previously undisclosed evidence when trial was either imminent or in progress; or (2) acted in bad faith, which is more than a mere lack of diligence. When making those determinations, courts should consider: (1) the prejudice or surprise in fact of the party against whom the excluded evidence would have been offered; (2) the ability of that party to cure the prejudice; (3) the extent to which waiver of the Fed. R. Civ. P. 37 sanctions would disrupt the orderly and efficient trial of the case or of other cases in the court; and (4) bad faith or willfulness of the party failing to make a required disclosure.

Civil Procedure > Summary Judgment > Motions for Summary Judgment > General Overview
Civil Procedure > Summary Judgment > Supporting Materials > Affidavits
[HN7] Fed. R. Civ. P. 56 permits parties bringing a motion for summary judgment to accompany that motion with supporting affidavits. Fed. R. Civ. P. 56(a). A party defending a motion for summary judgment may also employ supporting affidavits. Fed. R. Civ. P. 56(b). Supporting affidavits are subject to several requirements.

Civil Procedure > Summary Judgment > Supporting Materials > Affidavits
[HN8] In a motion for summary judgment, supporting affidavits must be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated therein. Fed. R. Civ. P. 56. Supporting affidavits must be brought in good faith; if a litigant offers a supporting affidavit in bad faith or solely for the purpose of delay, the court shall forthwith order the party employing them to pay to the other party the amount of the reasonable expenses which the filing of the affidavits caused the other party to incur, including reasonable attorney's fees, and any offending party or attorney may be adjudged guilty of contempt.

Civil Procedure > Summary Judgment > Motions for Summary Judgment > General Overview
Civil Procedure > Summary Judgment > Supporting Materials > Affidavits
[HN9] In a summary judgment motion, supporting affidavits may not clearly contradict prior sworn testimony. To allow parties to file supporting affidavits that contradicted prior testimony would be to allow them to subvert the purpose of motions for summary judgment. Courts may therefore disregard such affidavits. For a court to disregard and strike an affidavit, however, the contradiction must be clear; an affidavit that explains rather than contradicts prior testimony should not be disregarded. Generally, courts will only disregard an affidavit if the contradiction relates to questions actually posed to the witness. Nevertheless, courts may disregard an affidavit even if the witness was not explicitly examined on an issue, if allowing the affidavit to stand would change the flavor and theory of the case by introducing new causes of action or entirely new theories of recovery not previously disclosed.

Civil Procedure > Summary Judgment > Motions for Summary Judgment > General Overview
Civil Procedure > Summary Judgment > Supporting Materials > Affidavits
[HN10] In the context of a summary judgment motion, even if an affidavit does conflict with prior testimony, courts should not strike it if it satisfactorily explains the contradiction in terms of a mistake made while previously testifying.

Civil Procedure > Discovery > Disclosures > General Overview
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN11] It is required that expert reports provide a complete statement of all opinions to be expressed. Fed. R. Civ. P. 26 also allows parties to supplement the opinions expressed in their experts' reports, so long as such changes are made in accordance with the rule. Fed. R. Civ. P. 26(e)(1).

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN12] Fed. R. Civ. P. 26 requires that expert reports contain a complete statement of all opinions to be expressed and the data or other information considered by the witness in forming the opinions, while it only provides for the supplementation of information contained in an expert report. Fed. R. Civ. P. 26(a)(2)(B), (e)(1). When read in conjunction, these provisions might lead one to believe that the Rule allows only for the supplementation of information on which opinions are based, but not the opinions themselves. The Advisory Committee Notes state, however, that the rule's duty to supplement requires disclosure of any material changes made in the opinions of an expert from whom a report is required. Fed. R. Civ. P. 26 advisory committee's note (1993).

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN13] Supplementation of expert reports shall be disclosed by the time the parties disclosures under Fed. R. Civ. P. 26(a)(3) are due. Disclosures pursuant to Fed. R. Civ. P. 26(a)(3) shall be made, unless otherwise directed by the court, at least 30 days before trial. Fed. R. Civ. P. (a)(3).

Civil Procedure > Counsel > General Overview
Civil Procedure > Discovery > Disclosures > General Overview
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN14] Fed. R. Civ. P. 26 requires that expert reports be prepared and signed by the witness. Fed. R. Civ. P. 26(a)(2)(B). Fed. R. Civ. P. 26 advisory committee's notes state that the rule does not preclude counsel from providing assistance to experts in preparing the reports. Fed. R. Civ. P. 26 advisory committee's notes (1993). Nevertheless, Fed. R. Civ. P. 26(a)(2)(B) does not contemplate blanket adoption of reports prepared by counsel or others.

Civil Procedure > Pleading & Practice > Defenses, Demurrers, & Objections > Motions to Strike > General Overview
[HN15] In order to preclude a party from presenting evidence, the Third Circuit requires that the offending party must have: (1) revealed previously undisclosed evidence when trial was either imminent or in progress; or (2) acted in bad faith, which is more than a mere lack of diligence.

Civil Procedure > Summary Judgment > Supporting Materials > Affidavits
Civil Procedure > Sanctions > General Overview
Legal Ethics > Sanctions > General Overview
[HN16] Fed. R. Civ. P. 56(g) makes the filing of an affidavit in bad faith a sanctionable act that justifies holding a party or an attorney in contempt.

COUNSEL: For CHARLES D. STEIN, PLAINTIFF: JANICE V. QUIMBY-FOX, JOHN M. ARMSTRONG, SCHNADER, HARRISON, SEGAL & LEWIS, PHILA, PA USA.

For FOAMEX INTERNATIONAL, INC., FOAMEX L.P., FOAMEX CARPET CUSHION, INC., GENERAL FELT INDUSTRIES, INC./GFI-FOAMEX, MARSHALL S. COGAN, DEFENDANTS: GAYLE G. GOWEN, PHILADELPHIA, PA USA. GLEN R. STUART, MORGAN, LEWIS & BOCKIUS, PHILADELPHIA, PA USA.

JUDGES: JAMES McGIRR KELLY, J.

OPINIONBY: JAMES McGIRR KELLY

OPINION:

MEMORANDUM AND ORDER

J. M. KELLY, J.

Presently before the Court are a Motion to Strike and a Motion to Preclude, both of which were filed by the Defendants, Foamex International, Inc., Foamex L.P., Foamex Carpet Cushion, Inc., Trace International Holdings, Inc., General Felt Industries, Inc., GFI-Foamex and Marshall S. Cogan (collectively referred to as the "Defendants"). In this case, the Plaintiff, Charles D. Stein ("Stein"), filed suit against the Defendants, alleging vio-

lations of several environmental statutes. Stein served an Expert Report in support of his claims. The Defendants subsequently filed a Motion for Partial Summary Judgment. The Defendants [*2] assert that, in order to survive the Motion for Summary Judgment, Stein's expert filed an Affidavit that clearly contradicts the opinions expressed in his Expert Report. The Defendants have therefore filed the instant Motions. For the following reasons, those Motions are granted.

I. BACKGROUND

Stein is the owner of a twenty-two acre industrial property located in Philadelphia. The Defendants or their predecessors had leased that property from Stein for forty years. As part of their operations, the Defendants installed several underground storage tanks on the property. Stein alleges that, at some time in 1996 while the Defendants were occupying his property, it became contaminated. Stein filed his Complaint against the Defendants, alleging, among other state law claims, violations of several federal environmental statutes. Stein seeks compensation for the damages allegedly caused to his property, as well as his investigative, remedial and legal fees.

Stein had originally hired Sadat Associates ("Sadat") to perform environmental investigations on his property. Sadat prepared a May 1999 Site Characterization Report, which concluded that some vinyl chloride had been released [*3] on Stein's property. By Order of this Court, Stein had to serve any expert reports in this case no later than December 1, 2000. Stein ultimately chose Gary Brown ("Brown"), not Sadat, as his expert. Stein served Brown's Expert Report in a timely manner. Stein did not supplement that Expert Report before December 1. The Defendants deposed Brown on February 28, 2001.

Brown's Expert Report identified five areas of concern on Stein's property. See Brown Expert Report at 3. Brown summarized the first area of concern as "soils and groundwater impacted by releases of petroleum from the Fuel Oil Tanks and/or Outside Parrafin Tanks." Id. Describing this area of concern, Brown's Expert Report mentions only parrafin oil releases near the Outside Parrafin Oil Tank. Id. at 2, 4, 8. The Expert Report stated that "the foregoing areas of concern constitute releases or threatened releases of hazardous substances or petroleum." Id. at 13. Brown's Expert Report also concluded that the alleged "parrafin oil free product release at this site constitutes a substantial endangerment to human health and/or the environment . . . ." Id. When read in conjunction, these different sections [*4] of Brown's Expert Report clearly opine that parrafin oil on the property constitutes a release or threatened release that was a substantial endangerment to human health or the environment.

Importantly, nowhere does the Expert Report mention vinyl chloride as an area of concern. Although Sadat's Site Characterization Report mentioned the presence of vinyl chloride, and Brown's Expert Report mentioned the Site Characterization Report as a reference, the Expert Report neither adopted those particular findings nor vouched for their reliability. Indeed, the Expert Report does not expressly refer to that particular conclusion at all. Rather, the Expert Report simply mentions that Sadat had performed work for Stein.

The Defendants filed a Motion for Partial Summary Judgment on March 14, 2001. Briefly stated, the Defendants argued that Stein's federal statutory claims must fail because he had not presented evidence of a threshold amount of proscribed contamination. Specifically, the Defendants argued that, in order to recover, Stein would have to prove that there was an imminent and substantial environmental endangerment, and that the costs of Stein's environmental investigation work were [*5] necessary to address the release or threatened release of hazardous substances. See Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), *42 U.S.C. § 9607*(a)(4)(B) (1994); Resource Conservation and Recovery Act (RCRA), *42 U.S.C. § 6972*(a)(1)(B) (1994).

The Court granted several extensions of time in this case. Finally, on March 22, 2001, pursuant to a stipulation of the parties, the Court ordered that the case would be placed in the trial pool on May 6, 2001.

Stein then filed a Brief in Opposition to the Defendants' Motion for Partial Summary Judgment on April 6, 2001. Attached to that Brief was an Affidavit of Brown. This Affidavit asserted that: (1) there has been a release or threatened release of vinyl chloride on Stein's property; (2) the release constituted "an actual and significant threat to human health and the environment"; (3) the Defendants caused the release; and (4) certain monitoring and investigative activities on Stein's property, performed by Sadat and later by Brown, were necessary to address the release and threatened release of hazardous substances. See Brown Aff. PP 7-9, 13, [*6] 24-25.

The Defendants believe that Brown's Affidavit contradicts his Expert Report and deposition testimony, and was filed for the sole purpose of allowing Stein to survive the Defendants' Motion for Partial Summary Judgment. They therefore ask the Court to strike the Affidavit and preclude Brown from testifying about opinions not originally expressed in his first Expert Report.

II. STANDARDS OF REVIEW

1. The Defendants' Motion to Preclude

[HN1] *Federal Rule of Civil Procedure 26* requires that parties disclose the identity of any expert witness who may be used at trial. *Fed. R. Civ. P. 26(a)(2)(A)*. That disclosure must also be accompanied by a "written report prepared and signed by the witness." Id. (a)(2)(B). The expert report "shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor," as well as "the data or other information considered by the witness in forming the opinions . . . ." Id. Assuming the court establishes a schedule for such disclosures, parties must disclose their expert reports "at the times and in the sequences directed by the court." Id. (a)(2)(C).

[HN2] Rule 26 also imposes a duty to supplement [*7] expert reports. Id. ("The parties shall supplement these disclosures when required under subdivision (e)(1)."). Specifically, [HN3] Rule 26(e)(1) provides that:

> [a] party is under a duty to supplement at appropriate intervals its disclosures under subdivision (a) if the party learns that in some material respect the information disclosed is incomplete . . . . With respect to testimony of an expert from whom a report is required . . . the duty extends both to information contained in the report and to information provided through a deposition of the expert . . . .

Id. (e)(1). [HN4] Any additions or changes to the information contained in an expert report "shall be disclosed by the time the parties disclosures under Rule 26(a)(3) are due." Id. Disclosures pursuant to Rule 26(a)(3) shall be made, unless otherwise directed by the court, at least thirty days before trial. Id. (a)(3).

[HN5] Failure to properly disclose or supplement information in accordance with Rule 26 can result in sanctions pursuant to *Federal Rule of Civil Procedure 37(c)(1)*. See *Fed. R. Civ. P. 37(c)(1)*. Rule 37 provides that "[a] party that without substantial justification fails to disclose [*8] information required by Rule 26(a) or 26(e)(1) . . . is not, unless such failure is harmless, permitted to use as evidence at a trial . . . any witness or information not so disclosed." Id. Rule 37 provides for other sanctions as well, and the determination of which sanction to impose is within the sound discretion of the trial court. *Newman v. GHS Osteopathic, Inc., 60 F.3d 153, 156 (3d Cir. 1995)*.

[HN6] Discretion notwithstanding, "the exclusion of critical evidence is an extreme sanction." *Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894, 905 (3d Cir. 1977)*. Indeed, the United States Court of Appeals for the Third Circuit requires more than a literal violation of Rule 26; before a court preludes a party from presenting certain evidence at trial, it must first find that the party: (1) revealed previously undisclosed evidence when trial was either imminent or in progress; or (2) acted in bad faith, which is more than a mere lack of diligence. See, e.g., *In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 791-93 (3d Cir. 1994); In re TMI Litig. Cases Consol. II, 922 F. Supp. 997, 1004 (M.D. Pa. 1996)*. When [*9] making those determinations, courts should consider: (1) the prejudice or surprise in fact of the party against whom the excluded evidence would have been offered; (2) the ability of that party to cure the prejudice; (3) the extent to which waiver of the Rule 37 sanctions would disrupt the orderly and efficient trial of the case or of other cases in the court; and (4) bad faith or willfulness of the party failing to make a required disclosure. Id.; *In re Paoli, 35 F.3d at 791; Pennypack, 559 F.2d at 905*.

2. The Defendants' Motion to Strike

[HN7] *Federal Rule of Civil Procedure 56* permits parties bringing a motion for summary judgment to accompany that motion with supporting affidavits. *Fed. R. Civ. P. 56(a)*. A party defending a motion for summary judgment may also employ supporting affidavits. Id. (b). Supporting affidavits are subject to several requirements.

First, [HN8] supporting affidavits must be "made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated therein." Id. (e). Second, supporting affidavits must [*10] be brought in good faith; if a litigant offers a supporting affidavit in bad faith or solely for the purpose of delay, "the court shall forthwith order the party employing them to pay to the other party the amount of the reasonable expenses which the filing of the affidavits caused the other party to incur, including reasonable attorney's fees, and any offending party or attorney may be adjudged guilty of contempt." Id. (g).

Finally, [HN9] supporting affidavits may not clearly contradict prior sworn testimony. To allow parties to file supporting affidavits that contradicted prior testimony would be to allow them to subvert the purpose of motions for summary judgment. Courts may therefore disregard such affidavits. For a court to disregard and strike an affidavit, however, the contradiction must be clear; an affidavit that explains rather than contradicts prior testimony should not be disregarded. Compare *Hackman v. Valley Fair, 932 F.2d 239, 241 (3d Cir. 1991)* (affidavit conflicted with prior testimony), and *Martin v. Merrell Dow Pharm., Inc., 851 F.2d 703, 705 (3d Cir. 1988)* (same), and *Hyde Athletic Indus. Inc. v. Continental Cas. Co., 969 F. Supp. 289, 298 (E.D. Pa. 1997)* [*11]

(same), with *Giancristoforo v. Mission Gas & Oil Prods., Inc., 776 F. Supp. 1037, 1043 (E.D. Pa. 1991)* (affidavit clarified prior testimony). Generally, courts will only disregard an affidavit if the contradiction relates to questions actually posed to the witness. See *Farrell v. Planters Lifesavers Co., 206 F.3d 271, 284 (3d Cir. 2000); Videon Chevrolet, Inc. v. General Motors Corp., 992 F.2d 482, 488 (3d Cir. 1993)*. Nevertheless, courts may disregard an affidavit even if the witness was not explicitly examined on an issue, if allowing the affidavit to stand would change the "flavor and theory" of the case by introducing new causes of action or entirely new theories of recovery not previously disclosed. See *Pellegrino v. McMillen Lumber Prods. Corp., 16 F. Supp. 2d 574, 583 (W.D. Pa. 1996)* (concluding that counsel could not reasonably be held accountable for failing to uncover information through discovery because it greatly differed from nature of case as stated in complaint). Finally, [HN10] even if an affidavit does conflict with prior testimony, courts should not strike it if it satisfactorily explains the contradiction [*12] in terms of a mistake made while previously testifying. See *Martin, 851 F.2d at 705.*

III. DISCUSSION

1. The Defendants' Motion to Preclude

1. Whether Stein Violated Rule 26

The Court must first determine whether Stein violated Rule 26, a condition precedent to the imposition of sanctions under Rule 37 that the Defendants assume and Stein apparently conceded without inquiry. It is clear that Stein timely disclosed the identity of Brown as his expert witness, and that Brown's Expert Report was timely served before the date set by the Court. Accordingly, Brown may testify at trial and may express all opinions clearly expressed in his Expert Report. n1

n1 The Court notes that the Expert Report does violate Rule 26 in that its disclosures were incomplete when made and were not, and have yet to be, formally supplemented by Stein. Specifically, expert reports should contain "a listing of any other cases in which the witness has testified as an expert at trial or by deposition within the preceding four years." *Fed. R. Civ. P. 26(a)(2)(B)*. At the hearing on these Motions, it became clear that Brown has withheld the name of at least one such case because it was purportedly "confidential." Tr. of Hr'g at 41. Even if Brown has not testified in that matter, but instead simply prepared an expert report, Stein has still violated Rule 26(e)(2) by failing to supplement Brown's answers to interrogatories on the issue of his involvement in similar environmental cases. As the Court has already remedied this failure by ordering additional discovery and directing Stein to pay the Defendants' costs associated with a related Motion to Compel, the Court will not discuss this violation further.

[*13]

Whether Brown may testify concerning opinions expressed for the first time in his Affidavit, however, is another matter. The Affidavit was filed after the date set for the serving of expert reports. The Affidavit therefore does not qualify as an original expert report that could have been served in accordance with the Court's Scheduling Order. Nor could Stein have filed the Affidavit later than that time under Rule 26(a)(2)(c), which allows later filing for reports that are offered "solely to contradict or rebut evidence on the same subject matter identified" by the Defendants. See *Fed. R. Civ. P. 26 (a)(2)(C)*. This provision would have allowed Stein to present new theories or opinions at a later date. Stein has not argued that he offered Brown's Affidavit as a rebuttal opinion. Indeed, that argument is unavailable to Stein, as it would be internally inconsistent with his only argument thus far, namely that the Affidavit does not offer new opinions, but rather clarifies opinions already contained in the Expert Report.

Because the Affidavit cannot be considered an original expert report, the question therefore becomes whether it is an effective supplement to Brown's Expert Report. [*14] Despite Rule 26's requirement that [HN11] expert reports provide a "complete statement of all opinions to be expressed," the Rule also allows parties to supplement the opinions expressed in their experts' reports, so long as such changes are made in accordance with the Rule. See *Fed. R. Civ. P. 26(e)(1)*. n2 The Court finds that Brown's Affidavit was not filed in accordance with Rule 26.

n2 Interestingly, [HN12] Rule 26 requires that expert reports contain "a complete statement of all opinions to be expressed" and "the data or other information considered by the witness in forming the opinions," while it only provides for the supplementation of "information" contained in an expert report. *Fed. R. Civ. P. 26(a)(2)(B)*, (e)(1). When read in conjunction, these provisions might lead one to believe that the Rule allows only for the supplementation of information on which opinions are based, but not the opinions themselves. The Advisory Committee Notes state, however, that the Rule's duty to supplement "requires disclosure of any material changes

made in the opinions of an expert from whom a report is required . . . ." *Fed. R. Civ. P. 26* advisory committee's note (1993); see also *Fed. R. Civ. P. 26(a)(2)(c)* (providing for supplementation of all Rule 26(a)(2) "disclosures," not just "information" as stated in Rule 26(e)(1)).

[*15]

First, [HN13] supplementation of expert reports "shall be disclosed by the time the parties disclosures under Rule 26(a)(3) are due." Id. Disclosures pursuant to Rule 26(a)(3) shall be made, unless otherwise directed by the court, at least thirty days before trial. Id. (a)(3). Given that Stein's Pretrial Memorandum was to be filed with the Court on February 12, 2001, Brown's Affidavit, which Stein filed on April 6, was not timely filed as a supplement to his Expert Report. Moreover, even if the Affidavit had been timely served, n3 Stein would be unable to afford himself of Rule 26(e)(1), as he has argued throughout these proceedings that the Affidavit does not contradict Brown's Expert Report in any material respect. See id. (e)(1) (allowing supplementation of information in expert reports that is "incomplete or incorrect").

n3 Were it not for the fact that the Court set a date for pretrial disclosures, Stein would have been permitted to supplement Brown's Expert Report until thirty days before the instant case was to be called to trial. Id. (a)(3). By Order of March 22, the case's trial pool date was postponed until May 6, 2001. Brown's Affidavit, filed on April 6, would therefore have been filed, albeit fortuitously, as on the last permissible day.

[*16]

Second, Brown's Affidavit violates Rule 26 because Brown played no apparent role in preparing it. [HN14] Rule 26 requires that expert reports be "prepared and signed by the witness . . . ." Id. (a)(2)(B). The Advisory Committee Notes to Rule 26 state that the Rule "does not preclude counsel from providing assistance to experts in preparing the reports . . . ." *Fed. R. Civ. P. 26* advisory committee's notes (1993). Nevertheless, Rule 26(a)(2)(B) "does not contemplate blanket adoption of reports prepared by counsel or others . . . ." 6 James Wm. Moore et al., Moore's Federal Practice P 26.23[4] (3d ed. 2000). In the instant case, Stein's counsel provided more than assistance in preparing Brown's Affidavit. Indeed, at the hearing on this matter, Brown conceded that Stein's counsel, not he, prepared the Affidavit. Tr. of Hr'g at 76. Brown never claimed to have played any substantial role in its preparation, other than signing it. Although Brown implicitly referred to the existence of a second draft of the Affidavit, he gave no testimony regarding the extent of his involvement in the preparation of that draft. Moreover, the Affidavit was only filed in response to the Defendants' Motion for [*17] Partial Summary Judgment, and would not have been filed otherwise. While the language of the Affidavit explicitly mirrors the language of the federal statutes implicated in this case, Brown repeatedly testified that he was unfamiliar with the applicable legal standards under those statutes. See, e.g., id. at 45. Finally, Stein, although afforded ample opportunity to do so, offered no evidence that Brown prepared the Affidavit in any meaningful way. Accordingly, the Court finds that Brown's Affidavit violates Rule 26.

2. The Appropriate Remedy Under Rule 37

The Court has discretion in selecting the appropriate sanction for violations of Rule 26. [HN15] In order to preclude a party from presenting evidence, however, the Third Circuit requires that the offending party must have: (1) revealed previously undisclosed evidence when trial was either imminent or in progress; or (2) acted in bad faith, which is more than a mere lack of diligence. See, e.g., *In re Paoli, 35 F.3d at 793; In re TMI Litig., 922 F. Supp. at 1004.* The Court finds that preclusion of this evidence is appropriate because the Affidavit was filed in bad faith and the Defendants [*18] have been prejudiced by its late filing. n4

n4 Although the Affidavit was filed after this case was placed in the trial pool, the Court had yet to rule on two still- pending Cross-Motions for Partial Summary Judgment. Accordingly, Stein did not file the Affidavit when trial was imminent.

In essence, Stein would have the Court allow him to file preliminary expert reports and then freely supplement them with information and opinions that should have been disclosed in the initial report. That result would effectively circumvent the requirement for the disclosure of a timely and complete expert report. See, e.g., *Keener v. United States, 181 F.R.D. 639, 642 (D. Mont. 1998).* The concept of preliminary expert reports is contrary to the policies underlying Rule 26. See *In re TMI Litig., 922 F. Supp. 997, 1005 n.9; Smith v. State Farm Fire & Cas. Co., 164 F.R.D. 49, 53-54 (S.D. W. Va. 1995).* Allowing preliminary expert reports as a matter of course would afford litigants [*19] an opportunity to "mold their expert reports to meet [their opponent's] legal challenges." *In re TMI Litig., 922 F. Supp. at 1005 n.10.* Such was the case here. Brown's Affidavit was only filed in response to the Defendants' Motion for Partial Summary Judgment, and was carefully tailored, by

Stein's counsel, to dovetail with the statutory requirements the Defendants claimed Stein had failed to prove.

Although given the chance to do so, Stein offered no persuasive justification for the filing of Brown's Affidavit. Moreover, as is discussed at fuller length below, the opinions expressed in the Affidavit contradict those expressed in Brown's Expert Report. Finally, instead of supplementing Brown's expert opinions formally through an amended or supplemented expert report, Stein filed the Affidavit as an attachment to Stein's opposition to the Defendants' Motion for Partial Summary Judgment. Those facts, coupled with Stein's other Rule 26 violations and his inability to meet Court-imposed deadlines, demonstrate bad faith. n5 Simply stated, the work of Brown and Stein's counsel exceeds a mere lack of diligence. Id.

n5 As noted above, Brown's Expert Report, and the attempted supplement thereto, neglected to disclose certain information because it was purportedly confidential. Tr. of Hr'g at 41. Moreover, Stein filed his Pretrial Memorandum on March 8, 2001, despite the Court's unambiguous Order that it be filed no later than February 12.

[*20]

The Court finds that precluding this evidence is the most appropriate remedy for Stein's bad faith. Importantly, this ruling will not prevent all of Stein's claims from being heard by a jury; Stein may still rely on the opinions expressed by Brown in his Expert Report and, because the Defendants have only filed a Motion for Partial Summary Judgment, several of his claims will remain intact even assuming this ruling affects Stein's statutory claims. Accordingly, the Court will preclude Stein from relying on Brown's newly disclosed opinions at trial or in support of any motions filed with this Court.

2. The Defendants' Motion to Strike

Although the issue of the Defendants' Motion to Strike has largely been rendered moot by the Court's decision that Stein filed his Affidavit in bad faith, n6 the Court further finds that the Affidavit should be stricken from the record because it contradicts Brown's Expert Report, adding so many new opinions that it changes the flavor of the case from the one presented solely by Brown's Expert Report and depositions.

n6 See [HN16] *Fed. R. Civ. P. 56(g)* (making filing of affidavit in bad faith sanctionable act that justifies holding party or attorney in contempt). The Court notes that the Defendants have not asked the Court to impose these particular sanctions.

[*21]

In his Expert Report, Brown offered, among other opinions, an expert opinion that parrafin oil on Stein's property constituted a release or threatened release that substantially endangered human health or the environment. Nowhere does Brown's Expert Report mention the existence of a release or threatened release of vinyl chloride as an area of concern. The Defendants, based on Brown's Expert Report and deposition testimony, n7 could not have been on notice that Stein planned to base their liability on the existence, or threatened existence, of vinyl chloride. By contrast, Brown's Affidavit, which was filed after the Defendants filed their Motion for Partial Summary Judgment, offers many opinions concerning the presence of vinyl chloride and its associated health risks. Specifically, Brown's Affidavit opines that: (1) there has been a release or threatened release of vinyl chloride on Stein's property; (2) the release constituted "an actual and significant threat to human health and the environment"; (3) the Defendants caused the release; and (4) certain monitoring and investigative activities on Stein's property were necessary to address the release and threatened release of hazardous [*22] substances including, ostensibly, vinyl chloride. See Brown Aff. PP 7-9, 13, 24-25. None of these opinions appeared explicitly in Brown's Expert Report. n8

n7 For example, at his deposition, Brown stated that Stein's environmental investigations had not complied with CERCLA requirements because "the National Contingency Plan in something that deals with releases. When you investigate things and there isn't anything there by definition there isn't a release or threatened release . . . . This is not a federal . . . context like that." Brown Dep. at 239.

n8 While Brown's Expert Report stated that the nature and cost of the work on Stein's property were reasonable, Brown Expert Report at 13, it did not opine that such work was necessary in response to a release or threatened release of vinyl chloride.

Of course, Brown's Expert Report does refer to Sadat's Site Characterization Report, which mentions the existence of vinyl chloride on Stein's property. But Brown's Expert Report did not refer to that particular [*23] finding by Sadat, much less adopt it or vouch for its credibility. Indeed, Sadat's Site Characterization Report is twenty-eight pages long; simply referring to the

document in its entirety could not have put the Defendants on notice that Brown intended to express that particular opinion at trial. The filing of Brown's Affidavit altered the nature of these proceedings in a way that the Defendants, based on Brown's Expert Report and deposition, could not have anticipated. While the Affidavit may not conflict with Sadat's Site Characterization Report, it certainly conflicts with Brown's Expert Report. Brown never adopted Sadat's findings, and the mere mentioning of Sadat's Site Characterization Report as a reference document does not allow Brown, at this late juncture, to materially alter his intended expert testimony at trial.

Brown's Affidavit contradicts his Expert Report and deposition, and does not explain the contradiction in terms of a mistake in Brown's reducing his Expert Report to writing. Allowing Stein to file this contradictory Affidavit would allow him to undermine the purpose of motions for summary judgment. The Court will therefore strike the Affidavit from the record [*24] in this case. See *Hackman, 932 F.2d at 241; Pellegrino, 16 F. Supp. 2d at 583.*

ORDER

AND NOW, this day of August, 2001, in consideration of the Motion In Limine To Preclude Expert Opinions Not Expressed in the November 30, 2000 Expert Report of Gary Brown, filed by the Defendants, Foamex International, Inc., Foamex L.P., Foamex Carpet Cushion, Inc., Trace International Holdings, Inc., General Felt Industries, Inc., GFI-Foamex and Marshall S. Cogan (collectively referred to as the "Defendants") (Doc. No. 29), the Response of the Plaintiff, Charles D. Stein ("Stein"), and the Reply thereto, and in consideration of the Defendants' Motion to Strike the April 4, 2001 Affidavit of Gary Brown (Doc. No. 27), the Response of Stein and the Reply of the Defendants, as well as arguments and evidence presented at a Hearing held before this Court on July 18, 2001, it is **ORDERED** that:

1. The Defendants' Motion to Preclude is **GRANTED**. Stein is precluded from presenting expert testimony regarding matters or opinions not specifically and expressly contained in Brown's Expert Report, and from relying on such matters or opinions [*25] in support or defense of any motion before this Court.

2. The Defendants' Motion to Strike is **GRANTED**. The Affidavit of Gary Brown, filed as an attachment to Stein's Brief in Opposition to the Defendants' Motion for Partial Summary Judgment, shall be stricken from the record of this case.

3. Stein and the Defendants may, no later than fifteen (15) days after the date of this Order, submit a memorandum to the Court explaining the party's position on the effects of this Order on the Cross-Motions for Partial Summary Judgment still pending before this Court.

BY THE COURT:

JAMES McGIRR KELLY, J.

IN THE UNITED STATES DISTRICT COURT FOR THE

DISTRICT OF MASSACHUSETTS

DEPUY MITEK INC., a Massachusetts Corporation, Plaintiff, vs. ARTHREX, INC., a Delaware Corporation, and PEARSALLS LIMITED, a Private Limited Company of the United Kingdom, Defendants.	:	Civil Action No. 04-12457

Washington, D.C.

Wednesday, June 21, 2006

Videotape Deposition of:

DR. NORM GITIS,

The witness, was called for examination by counsel for the Plaintiff, pursuant to notice, commencing at 8:15 a.m., at the law offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, Northwest, Washington, D.C., before Dawn A. Jaques, Certified Shorthand Reporter and Notary Public in and for the District of Columbia, when were present on behalf of the respective parties:

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Dr. Mukherjee, Dr. Burks, and/or Dickstein Shapiro Morin & Oshinsky concerning the lawsuit.
Have you produced those?
A. Yes, I did.
Q. Do you have invoices that you've charged in this matter, any bills that you've sent to someone?
A. I do have invoices, but I did not bring them. I did not produce them.
Q. Okay. And who did you send those to, to the law firm or Anthrex?
A. To the law firm.
Q. Request No. 5 is all documents and things concerning this lawsuit. Have you produced all the documents and things that you have concerning this lawsuit?
A. Yes.
Q. Turn to the next page, Things To Be Produced says, Request No. 1, all tested and untested samples referred to in the Comparative Suture Testing. Do you see that?
A. Yes.
Q. Have you produced all the FiberWire samples that remain from the testing that you did?
A. Yes.

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Q. So you have no more FiberWire samples in your possession?
A. None.
Q. None? Did you give any to counsel within the last week or two?
A. Several weeks ago, but not necessarily within the last week.
Q. So just to confirm, you produced samples to us. Is there no other samples?
MR. TAMBURO: Nothing else.
(DePuy Mitek Exhibit No. 381 was marked for identification.)
BY MR. BONELLA:
Q. Next I'll show you DuPuy Mitek Exhibit 381. It's entitled "Comparative Suture Testing" from CETR. I'll ask you if you recognize DePuy Mitek Exhibit 381?
A. Yes, I do.
Q. And what is DePuy Mitek Exhibit 381?
A. Our test report on the comparative suture testing.
Q. Are you hired as an expert in this case? Are you being asked to serve as an expert?
A. I've been asked to produce -- to test and to produce a test report. Whether you call it

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expert or not, I don't --
Q. Have you been asked to provide opinions, or have you just been asked to perform certain tests and provide the test results?
A. Not -- I have not been asked to provide any opinions, only to test and to produce test results.
(DePuy Mitek Exhibit No. 382 was marked for identification.)
BY MR. BONELLA:
Q. Next I'd like to show you DePuy Mitek Exhibit 382. It's Bates numbers CETR 76 through 79. It's four pages. I ask you if you recognize Exhibit 382?
A. Yes, I do.
Q. What is DePuy Mitek Exhibit 382?
A. These are additional data plots to the earlier produced test report.
Q. Is this another report that you provided?
A. It's not a new report. It's just -- what happened with the original test report, we produced all the data in the table, but only typical data in the data plot, and my understanding was that we have been requested to

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provide all the data plots, so these additional data are just the entire data plots of all the test data generated at Center For Tribology.
Q. DePuy Mitek Exhibit 382, did you sign anything that says it's part of your report, or have you signed something saying it's a supplement to your report?
A. No, I did not. I just provided this data without signature, sorry.
Q. Okay. So in front of you is DePuy Mitek Exhibit 381 and 382. Do DePuy Mitek Exhibits 381 and 382 detail all the work that you've done in this case?
A. Yes.
Q. And do they contain all the facts and things that you expect to testify about?
A. Yes, they do.
Q. Is there anything you expect to testify about that's not in DePuy Mitek Exhibit 381 and 382?
A. No.
Q. Have you been asked to prepare any more reports or to provide any supplements or changes to Exhibits 381 and 382?
A. Not as far as I know.

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Q. Okay. So you have no opinions about the patent that's involved in this case?
A. No, I do not.
Q. The project goal it says -- is that the description of what you were asked to do?
A. Yes, pretty much.
Q. Were you asked to do anything other than what's stated in the project goal?
A. It's stated as performing comparative mechanical and tribological testing of two types of Fiberwire. Yes, nothing else has been asked me to do.
Q. That was nothing else --
A. Nothing else has been asked.
Q. Okay. Are you experienced in doing tensile tests?
A. Yes.
Q. Okay. Have you done tensile testing on sutures before this case?
A. Yes.
Q. Okay. Have you done tensile tests on other textiles before this case?
A. I don't remember.
Q. In the other expert testing that you've done, did you do any testing on -- did you do any

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expert opinions on patents?
A. Yes, I did.
Q. You did? Okay. Is that infringement?
A. Yes.
Q. How about validity?
A. Yes.
Q. But you weren't asked to do that in this case?
A. That's correct. I was specifically told that there is an expert witness, Dr. Mukhergee, who will provide opinions on the patent, and I would be -- my role would be only to do testing and to present the test report.
Q. Tribology is the study that deals with design friction wear and lubrication of interacting surfaces and relative motion; is that right?
A. Yes.
Q. Okay. Do you recall -- I think you said no, but just to check, you don't recall the relative numbers and the data that you obtained for any of the tests you did for Ethicon and U.S. Surgical?
A. I am very sorry, I don't remember that.
Q. Going back to your report, Exhibit 381,

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in the first page, second paragraph, you said 90 percent of CETR revenue is from design and sales of equipment; is that right?
A. Yes.
Q. And 10 percent is from testing/consulting services, right?
A. Yes.
Q. And then you say that you've done -- you supplied equipment to Ethicon, right?
A. Yes.
Q. Do you know what percentage of revenue that was generated from Ethicon was for equipment as opposed to testing/consulting services?
A. For Ethicon?
Q. Yeah.
MR. TAMBURO: Objection, vague. You mean his revenue?
MR. BONELLA: CETR's revenue.
THE WITNESS: I'm confused, yeah.
BY MR. BONELLA:
Q. The revenue that CETR has generated from Ethicon, what percentage was from equipment sales to Ethicon, what percentage was for consulting services?
A. I don't remember the exact numbers, but

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they're obviously in our database, easy to obtain, but my wild guess is very close to our average numbers, 90 percent from equipment sales and 10 or less percent from testing.
Q. Okay. In your report you say that you're charging $2,500 per day and $10,000 per week for regular lab testing services, and double prices for priority?
A. That's correct.
Q. In this case, did you charge the priority?
A. For Ethicon?
Q. No, no, for your work in this case.
A. Partly, yes.
Q. Partly, yes?
A. Yes.
Q. For the testing, did you charge the priority?
A. Yeah, only for the testing.
Q. Okay. But not for the report?
A. Not for the rest of the report -- of the work, no.
Q. Okay. And you say $2,500 per day is what you're charging?
A. Actually, when we did the work for

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Q. Thank you. The testing that you did in connection with this case in your reports, who actually did the testing?
A. I did it together with two engineers in my lab.
Q. Okay. And what engineers?
A. Michael Vinogradov and Vishal Khosla.
Q. Can you spell their names, please?
A. Michael V-I-N-O-G-R-A-D-O-V, Vinogradov, and Vishal K-H-O-S-L-A, Khosla. One is from Russia, one is from India.
Q. I'm going to guess Mr. Vinogradov is from Russia?
A. Good guess.
Q. What did Mr. Vinogradov do with respect to the test? What was his role?
A. He helped to set up the testers and modules, and he did some of the tests together with me.
Q. What tests did Mr. Vinogradov do?
A. Most of the tests, or maybe all of the tests we kind of did together.
Q. So Mr. Vinogradov was involved in all the tests?
A. Yeah, and same thing with Mr. Khosla.

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Q. How did their roles, Mr. Vinogradov and Mr. Khosla's roles, differ?
A. Vinogradov is a more senior member of the team, and he was involved fully in all the tests that we did for Ethicon and U.S. Surgical, and he was the only one who remembered something from those old tests.
So Michael was more senior. He was helping mostly in setting up the tests, and Vishal was helping mostly in running the tests, and I was like in and out. I was not there hundred percent of the time.
Q. Okay. You weren't there 100 percent of the time for the set-ups; is that right?
A. For all of it, for the set-ups and the test. So they will do the set-up, I would come approve or not approve, and then we would start running tests. I would come out, come back and see what is happening.
Q. Did you approve each set-up after it was done before the test was run?
A. Yeah, of course.
Q. You visually looked at each set-up?
A. Yes.
Q. And in terms of when the tests were

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running, most of these tests took less than a minute, right, actual running time?
A. Not really. Depends on what you call the running. You have to set up the specimen, and for some of them you have to make notes, so most of them took several minutes. So, yeah, I was in and out of the room during this test.
Q. And what percentage of the test did you actually see?
A. Maybe between 25 and 50 percent.
Q. Okay. Is there any of the tests that you didn't actually witness the test being done of the tests that were done? Let me ask a better question.
There's pliability tests that you've described. Were you present for at least some of the actual testing of the pliability samples for pliability?
A. Yes, I was present in at least some of each and every test, each type of test.
Q. Okay. So you weren't present the whole time for this set-up and loading of each sample; is that right?
A. That's correct.
Q. And from the tests that were done, data

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was generated, correct?
A. Yes.
Q. Okay. And all the data that was generated, was that computer generated?
A. Yes.
Q. And then from the computer-generated data, some calculations and results were presented?
A. Yes.
Q. Who did the calculations?
A. Two of them, Michael and Vishal.
Q. Okay. What was your involvement in the calculations?
A. We discussed the formula used, and I checked the results.
Q. Did you check every result, or just kind of spot check it?
A. I checked most of the results.
Q. Okay. Did you instruct Mr. Vinogradov and Mr. Khosla as to how to -- as to what formulas to use and how to generate the results from the data?
A. How to generate results, I don't have to instruct them. They know how to do it.
What formula to use, maybe it was not my

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A. The only knowledge of structure -- or knowledge, if it may be called structure or not, was taken SEM photos of the fibers.
Q. Okay. Did you do any analysis to determine how the samples were manufactured?
A. No, I did not.
Q. Okay. Did you review any documents that describe how the samples were manufactured?
A. I reviewed deposition of Dr. Mukherjee, and it was -- part of it was somewhere related to production, but I didn't pay much attention.
Q. Anything else you reviewed that had anything to do with manufacturing the FiberWire samples?
A. No.
Q. Now, the samples, the FiberWire samples were sent to you by Dickstein Shapiro?
A. Yes.
Q. And that's the law firm, right?
A. Yes.
Q. Okay. When the samples came to you, in what form were they in?
A. Sutures were on the spools, and both spools were in plastic bags inside a FedEx envelope.

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Q. Okay. And the coated sample was on one spool, and the uncoated was on another spool?
A. Yes.
Q. Were the spools labeled at all?
A. Yes.
Q. Were they -- one said coated, one said uncoated on it?
A. Yes, very clearly.
Q. Okay. I think my question became unclear. I'm going to ask it again.
So were the spools that you received from the law firm, one said coated on it; is that right?
A. Yes.
Q. And the other spool that you received from the law firm said uncoated on it?
A. I am sorry, I don't remember whether it said uncoated, but I remember that there was no doubt whatsoever to distinguish that one was coated, one was not, but I don't remember wording specifically on the label.
The spools have labels, and I don't remember wording on the labels.
Q. So the two spools you received from the law firm had labels that conveyed to you that one

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of the spools had coated FiberWire and the other spool had uncoated FiberWire?
A. Yes.
Q. Where are the spools?
A. My apologies, somehow we lost them.
Q. You lost them, okay.
A. Yeah, unless -- either we lost them or we sent them, the samples, to the expert witness, but somehow they disappeared from our lab.
Q. Okay. So at one point you had the samples. Then did you -- you used some of the sample for testing, right, for your own CETR testing, right?
A. Yes.
Q. And you sent some samples to a Dr. Burks?
A. Yes.
Q. And the samples that you sent to Dr. Burks, were they on spools?
A. I do not remember at this second.
Q. Did you send samples to Dr. Mukherjee?
A. We did send samples to him, yes.
Q. What samples did you send to him?
A. Same thing, of coated and uncoated. And I don't remember, maybe one of the shipments was

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on the spools. I don't remember.
Q. Do you have any spools of your own that you put sample on?
A. No.
Q. So if you did send spools, they were the spools that you received?
A. On the original spools. We don't have any other spools in the building.
Q. So if you did send spools to a witness, they were on the spools that you received?
A. Correct.
Q. Okay. When you sent the samples to Dr. Burks, do you recall doing anything with those samples?
MR. TAMBURO: Objection, vague.
THE WITNESS: I do not.
BY MR. BONELLA:
Q. Do you recall like labeling them or segregating them in any way?
A. What happened personally, I was not involved in sending samples to either expert. They were sent by my engineer, my secretary, and so I -- this is why I am a little bit unclear whether they were sent on the spools or not.
Q. Do you remember doing anything to the

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and decided that this range is good.
Q Look at the graphs on 382. It looks like some of the graphs -- some of the samples you stopped before others. Do you see that?
A Yes.
Q Why is that?
A I don't remember.
Q Is that where you actually stopped?
A Yeah.
Q At the end of the pliability test data in your report, Exhibit 381, after the chart --
A Yes.
Q -- down here you say the stiffness of the coated sutures was found to be lower than that of the uncoated sutures. This suggested the coated sutures have higher pliability and thus facilitate better handling during surgical use.
Do you see that?
A Yes.
Q You used the word "suggest." Why did you use that word?
A Because personally I am not 100 percent convinced that the test used at Ethicon for stiffness is directly -- that the Ethicon definition of pliability and Ethicon definition of

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stiffness are exactly the way somebody at ASTM would specify it.
So I tried to be scientifically conservative, and I said that we found stiffnesses lower, and what is your understanding of pliability? If your understanding is the same as that of Rodeheaver and Ethicon, you will say that pliability is higher. If your understanding is different, you make your own conclusions.
Q How did you pick the two curves that are shown on page 4 of your report, Exhibit 381, for the pliability tests?
A They were more or less -- not mathematically, but visually typical for their groups.
Q Sample 2 you had, for the coated suture, at 7.53.
A Yes.
Q And sample 6 of the uncoated was 8.00. Do you see that?
A Yes.
Q Why were those two closer together than the other ones?
MR. TAMBURO: Objection, vague.
THE WITNESS: You're asking me why

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different samples produced not exactly the same result?
BY MR. BONELLA:
Q I'm asking you why No. 2 coated and No. 8 -- No. 6, uncoated, were closer together than the other ones?
MR. TAMBURO: Same objection.
THE WITNESS: I have no explanations. It depends on how they were made and on the uniformity of the manufacturing processes and uniformity of their history, and no samples are always the same.
This is why people do statistical analysis, and this is why we did our test and made our conclusions based on several samples, not just one sample of each group.
BY MR. BONELLA:
Q In your -- in the last -- in the bottom of that page under the Table 1 where you say this suggests that the coated sutures have higher pliability, then you say and thus facilitate better handling during surgical use.
You don't have any experience to draw the conclusion that they facilitate better handling during surgical use, do you?

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A Yeah, I don't have any experience. It's from the literature, not from my opinion.
Q Did you actually calculate the slopes yourself for the pliability test?
A My engineers calculated.
Q Did they actually calculate the pliability test data that's in the chart?
A Yes.
Q Did you check it?
A I believe I did.
Q You believe you did. Either no, you don't know, or you don't remember.
MR. TAMBURO: Objection, asked and answered.
MR. BONELLA: You can't believe. Either you know you checked it, or, no, you didn't check it?
MR. TAMBURO: That's untrue. You can have a belief and not be 100 percent sure either way. He gave you his answer.
THE WITNESS: Maybe it's a good definition. I don't remember 100 percent, but I am almost sure that I checked all the calculations in all the tests.
BY MR. BONELLA:

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labeled brass rod is?
A That's correct.
Q The knot was then subject to running down by pulling at a constant speed of one and-a-half millimeters per second on the longer free end in the testing machine as shown in Figure 7, right?
A Yes. The free end was like upper end, and the loop was like the lower end of the suture on Figure 7.
Q The loop is around the rod, right?
A Yes.
Q And then there's two ends?
A Right.
Q One was -- and you pulled on one end?
A Yeah, the longer end.
Q Okay. And the longer end, how did you attach that to something to pull on it?
A How we attached it to the -- to the upper specimen, with the same angle bracket as was shown in pliability test and knot strength test.
Q It doesn't show it.
A As you said, you can call it bolt and nut.
Q I'm sorry.

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A As you said previously, you can call it bolt and nut, how we clamp the suture.
Q I don't understand what you just said.
A Okay.
Q I don't understand what you're saying.
A Earlier when I described our clamp to clamp the suture, you asked me whether you can call it bolt and nut, and I said yes.
Q Okay. I see in the Figure 7, test set-up for the knot run-down, there's a brass rod in the upper fixture.
A Yes.
Q What was that used for? Looks like the suture is looped around it, no?
A Yes. Maybe it's wrong photo. It's photo from Figure 4. Maybe it's the right photo for the upper attachment is the same as in Figure 1.
Q Wait a minute, I'm confused now. Are you saying Figure 7 may not be the knot run-down test?
A Figure 7 is -- no, no. It's correct. Figure 7 is a knot run-down test. The loop was formed on the separate supplemental cylinder, was then transferred on the brass -- on the lower

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brass rod.
Q Yes.
A And then the free -- longer free end was just attached to the upper rod.
Q Attached to the upper brass rod?
A Yes.
Q How was it attached to the upper brass rod?
A I don't remember.
Q Was it tied in a knot?
A I don't remember. Most likely it was tied in a knot.
Q How about the lower -- how about the other end, what happened to the other end of the suture? What did you do with that?
A I believe it was cut like in all the referenced literature.
Q What do you mean cut? There's two ends of the suture that are in the half hitch, and one you said goes up --
A The longer ones, the free one, goes on the upper rod.
Q Okay. What happens to the lower one? What happens to the other end?
A I don't remember. We didn't describe

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here, and I don't remember.
Q Well, how is the knot running down? I mean, what's holding the other end? Something's got to hold the other end, right --
A Right.
Q -- if it's a run-down test.
A Right. Sorry, I don't remember.
Q So you can't exactly tell me how this test was done?
A I have to think about it. I don't remember.
Q Okay. How many kilograms in a newton?
A One kilogram is 9.8 newton.
Q Let me show you the first page of Exhibit 404 back at the knot slippage strength test. I'm going to shift gears on you here. There's a line at the 10-second point?
A Yes.
Q What is that line for, that vertical line?
A I do not remember.
Q Is someone looking at the slope before 10 seconds?
A I do not remember.
Q So in this test, the -- I guess you

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coated, right?
BY MR. BONELLA:
Q Right. So we're in the beginning of the curve.
A Right, in the very beginnings, yeah.
Q If the experiment --
A I have to think about this. I don't have an explanation.
Q It doesn't -- that data is not consistent with a constant velocity of 1 millimeter per second, right?
A That's true.
Q Let me ask you this. The curves -- if you go back to the non-slippage strength curve.
A Knot slippage strength, yes.
Q You ran a test for about 50 seconds, right?
A For almost a minute, yeah.
Q So if the -- if you ran the curve for 50 -- if you ran it for 50 seconds, the Z value should have gone up 50 millimeters?
A Right.
Q And that should be reflected in the data?
A Yeah.

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Q All right. Now let's go on to the friction test. The friction test you mounted a suture, used two sutures, one as an upper and one as a lower suture, right?
A Yes.
Q And you kind of rubbed them up against each other, if you will?
A Yes.
Q So the upper suture was moved on the lower one at a reciprocating length of 3 millimeters at a frequency of .5 hertz under a constant normal load of 2 newtons for 200 seconds, is that right?
A Not exactly. The lower suture was moved against the upper, but the rest is correct.
Q The lower was moved against --
A Well, no, I'm sorry. I'm sorry. In this case, you're right, the upper was moved, yeah.
Q Okay. So the lower suture was held stationary, and the other is moving laterally?
A Yes, correct, yeah.
Q Now, when you mounted -- so what fixture did you use in the -- what driver did you use in the upper part?

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A We used the X motion drive.
Q Okay. And the lower one was just a stationary?
A We attached a linear reciprocating drive, but then we decided not to use it, and we just used stationary and we used upper X for reciprocation.
Q And why did you decide that?
A I don't remember.
Q Would it matter whether both were moved or just one?
A No, no difference.
Q So you mounted the sutures, and what you have labeled in the diagram as suture holders?
A Yes.
Q What was the suture holder?
A It's a screw. You loop the suture around the screw, and by rotating the screw, you increase the tension on the suture.
Q Is it a metal bracket?
A Yes.
Q And how does the one end of -- one end of the holder has a screw; is that right?
A Yes.
Q And the other end doesn't have a screw?

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A Yes.
Q It does?
A Correct, only one has a screw.
Q Okay. How is the suture held at the end that doesn't have a screw?
A Just clamped.
Q Clamped?
A Clamped.
Q Clamped between two pieces of metal?
A Yes.
Q So at one end the suture is clamped between two pieces of metal, the other end you took the suture and you wound it around the screw?
A Looped around the screw, yeah.
Q And then you screwed the screw into a hole?
A Hole, yeah.
Q And that held --
A Into a nut, into a stationary nut, yeah.
Q Into a stationary nut?
A Yes.
Q Okay. Did you measure the clamping force on the suture?
A No.
Q Did you measure the torque or the force

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applied by the screw?
A No.
Q How do you know if the upper suture and the lower suture were under the same tension?
A By the number of rotations of the screw.
Q You're saying the screw is rotated the same amount for the upper suture and the lower suture?
A Not necessarily for the same amount, but between different samples, to ensure the same tension of different samples, we always rotated the screw on the same -- by the same number of revolution.
Q How about the upper and the lower?
A Same thing, for upper and for lower.
Q Isn't how much tension the suture was under in the bracket also a function of the force applied by the clamp?
A No, it's only function of the number of revolutions of the screw.
Q How did you know that you rotated the screw the same amount for each sample?
A Just manually made sure.
Q How did you do that? If I have a screw and I start rotating it, how do I know --

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A You just count number of rotations, that's it, number of revolutions.
Q How do you know you weren't off by a quarter turn or eighth of a turn or sixteenth of a turn or thirty-second of a turn?
A We have been doing this -- we have been using this type of tensioning holders for years for many samples, samples of tapes, samples of sutures, samples of fabrics, and results have been pretty consistent, so I believe that it's -- it gives pretty consistent tension.
Q My question is do you actually know that they were exactly the same exact spot screwed in the same exact amount?
A It's a little bit subjective, but it's still quite consistent.
Q You don't know that they were actually screwed in the same exact amount though, right?
MR. TAMBURO: Objection, asked and answered.
THE WITNESS: As I said, I know that they have been screwed by -- it was the same. This is what I started from saying, that an upper and lower were tensioned to the same amount. It's important for this test to maintain the same

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tension from sample to sample.
BY MR. BONELLA:
Q Yeah, but you're just doing it based on the person turning it at the same amount, right?
A Yes.
Q So if they turned it just a hair past, it may not be detectable based on our subjective --
A Maybe.
Q So the normal load was constant of 2 newtons; is that right?
A Yes.
Q So that's the force pushing down, right?
A Yes.
Q Is this machine set up to generate the coefficient of friction values?
A Yes.
Q It is? And is there an algorithm in the machine? There's an algorithm in the machine to calculate it?
A The sensor, our force sensor measures simultaneously and independently normal load and lateral friction force, and software simultaneously, real time, calculates friction coefficient as the ratio.

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Q And what is the calculation that the algorithm uses? What is the formula, the math?
A The math I just said, it's just ratio of friction force over normal load.
Q Friction force over normal load?
A Yeah.
Q And the normal load was always 2 newtons?
A Yes.
Q And the friction load you're saying is the force that was measured?
A Yes.
Q And how are you measuring that force? How are you measuring that friction force?
A We measured it with a force sensor or load cell installed above the upper suture.
Q So it's the load that was applied to the upper suture and the --
A The sensor has two -- the sensor has two sensors. One measures vertical, one measures horizontal, and we measure it in the same force sensor which is under the loading system above the upper suture.
Q Is the upper suture moving in one of the directions?

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amplitude of fluctuations.
Q Average amplitude of fluctuations. I don't understand what you mean.
A It consists of each and every point, but for the sake of Table 5, we talk only average from Figure 11 and average from Figure 8.
Q Are you saying you took the average from Figure 11 --
A Average amplitude. Average amplitude from Figure 8, average amplitude from Figure 11, and we took their average as amplitude for Table 5.
Q So you got the average amplitude for Figure 8 -- wait.
A Yeah, it's true.
Q It's difference in amplitudes, right? Chatter isn't the difference in amplitude?
A No, chatter is amplitude. Chatter is amplitude of fluctuations. So if you look -- for example, let's look at uncoated in Figure 11.
Uncoated in Figure 11 has amplitude from about .15 to about .17. It's .02. So amplitude is .02. Are you with me?
Q Are you saying basically you just looked at the graph, you drew a line that was along the

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highest peaks here, and then looked at the line on the bottom and said the amplitude is .02?
A Yes.
Q How did you know where to draw the line? Like the beginning part goes down the curve. Did you omit that part?
A You don't really do it manually on the plot. You do it in the computer automatically, and --
Q Let me back up. Did the computer generate the values, or did you calculate them or get them from the graph for chatter?
A Amplitude of fluctuations is automatically produced by the computer.
Q By the computer, okay. Is that shown in the --
A Unfortunately not because secondary parameters. The recorded data in our software is only the original data, like force displacement, but what you calculate, statistical analysis, unfortunately, is not recorded.
Q Is it gone?
A Yeah.
Q You don't have it anymore?
A So this is what you have table for.

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Q Is there some computer program that's in the machine that generates the difference in the amplitude for the Figure 8 and Figure 11 curves?
A Yes.
Q Can you tell me the math that is used to do that?
A The math will calculate the amplitude --
Q I mean, does it figure the average high point and the average low point, and then take the difference between the two, or does it take each high point with the next low point and take those differences and average them, or how does it work?
MR. TAMBURO: Objection, vague.
THE WITNESS: Can you please repeat?
BY MR. BONELLA:
Q Sure. One thing you could do, I just don't understand how the computer is doing this. One thing you could do is you could take this high point to the next low point, high point to low point, and you figure out that difference for each time and average them; or you can figure out what the high point was, the average high point and the average low point, and take the difference between those two.
A Yes.

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Q Or there could be some other way you could do this. I don't know.
A Yeah, I do not remember. I'm sorry.
Q You don't know?
A No.
Q How about for determining it from the other figure, Figure 08, do you know how that was done?
A Same thing.
Q If you look at the Table 5 chatter data --
A Yes.
Q Do you know why sample 6 had a chatter data value of 0.012 for coated, which was greater than the uncoated suture chatter data value? Do you know why?
MR. TAMBURO: Objection, calls for speculation.
THE WITNESS: Your question is whether -- I see it here. Yes, I see it.
BY MR. BONELLA:
Q Yeah. That's saying sample 6, coated, got a greater chatter value than sample 6, uncoated.
A Yes, I see it, yeah.

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Q Can you explain why?
A No, I cannot.
Q The next test is the tissue drag tests, right?
A Yes.
Q It says two types of tests were performed, dragging the suture through the hole made with a needle, and dragging the suture between two tightly clamped pieces of leather.
A Yes.
Q In both cases, the upper end of the suture was attached to the UMT upper bracket, providing the well controlled motorized dragging action. Do you see that?
A Yes.
Q Do you see the curves in Figure 13?
A Yes.
Q Are those for the tests for dragging the suture through the hole made with the needle? Are those for the tests of dragging the suture between two tightly clamped pieces of leather?
A These curves are result of needle.
Q Are what?
A In the case -- in the second case, without the needle.

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Q So Figure 13 is a tissue drag test without the needle test?
A Correct.
Q How about the Table 6 data?
A Same thing.
Q Where is the results of the tissue drag with the needle?
A We did not present them because average was the same.
Q So you did the tissue drag tests with the needle, you just didn't present the results?
A We started doing with the needle, then we switched to the clamp, we found no difference, and we continued with the clamp.
Q Yeah, okay. You did it with the needle, you didn't present the results. Do you still have the results?
A No, we do not.
Q What happened to them?
A We did not save them. I assume we overwrote the test file with the data from the clamp.
Q You overwrote -- you just said -- you just said you did the clamp first and the needle --

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A No, no, we started from the needle, then we decided to switch to just clamp and get rid of the needle, and we found results are the same, so we discarded needle and proceeded only with clamping the suture between two pieces of leather.
Q Do you have any results at all from the needle testing that we can look at to assess your statement that the results were the same?
A No, we do not have.
Q The test with the needle, let's do the -- I'm sorry, let's do the clamp test first. If I can call it the clamp test, is that okay, the tissue drag clamp test?
A Uh-huh.
Q So that was done by clamping a suture between two pieces of leather; is that right?
A Yes.
Q And how is the tension controlled on the clamp?
A I'm sorry, which tension?
Q The clamping the suture between two pieces of leather, right?
A Yeah.
Q And the clamp is a metal clamp with a nut and bolt, right?

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A Yes.
Q How are you controlling the tension or the forces that are applied by the clamp controlled by the nut and the bolt?
A We didn't control it.
Q You didn't control it, okay.
Now, so the suture is sandwiched, if you will, between two pieces of leather, right?
A That's correct.
Q And then the upper part of the suture is pulled; is that right?
A Pulled up, yeah.
Q And you used a 20 millimeter gauge length, right?
A Yes.
Q So is that the same for all samples?
A Is the same?
Q Was the 20 millimeter length the same for all samples for the clamp tissue drag?
A Yes.
Q And you did this test by pulling a constant rate. You did the tissue drag clamp test by pulling at a constant rate of 1 millimeter per second?
A Yes.

starts from some level of tensioning. Before motion starts in the tissue drag test, there is no real tensioning of the sutures.

BY MR. BONELLA:

Q I understand that, but have you ever seen tension tests where there's no preload?

A Tension test without pretensioning?

Q Without preload.

A It's very hard to do.

Q You open up a mechanical engineering textbook for college and you look at test -- stress/strain curves for tension tests that are presented, some of those go through zero you think?

MR. TAMBURO: Objection, vague, confusing, calls for speculation.

THE WITNESS: Which zero?

BY MR. BONELLA:

Q If it's stress versus strain, it starts at zero and goes up, no preload.

A For sutures?

Q Just for anything.

A Anything and sutures are two different things, or many different things.

Q Okay.

A If you want to do tension test of a solid metal or ceramic sample, you may or may not need preload, but if you want to do tension test of a suture, you have to have some level of tensioning, otherwise if it's completely slacked, then there's no tension test.

Q Okay. On the first -- on your tissue drag, after the force gets up to about 0.5 in the graph --

A Yes.

Q -- can you consider that a preload, and then go from 0.5 to the point at which suture movement goes?

A I have to think about that. That's a good question. I have to think about it. You caught me at the moment that I'm very tired today at the end of the day.

Q Okay. And all your data that you intend to talk about in this case and all the conclusions that you've drawn are all in your exhibit -- in the two reports that you presented?

A I presented only one report.

Q One report and the supplement.

A And supplement, yeah.

Q Yes?

A Yes.

Q Okay. Other than the tissue drag test with needle, did you do any other tests that weren't reported?

A No, we did not.

Q Were you asked to draw any opinions or conclusions about what caused the difference in the results?

MR. TAMBURO: Objection.

THE WITNESS: I was asked by you today, but I was never asked by Dickstein Shapiro.

MR. BONELLA: I don't have any questions.

MR. TAMBURO: No questions.

THE VIDEOGRAPHER: This deposition concludes at 5:18:10 and consists of four tapes.

(Whereupon, at 5:18 p.m., the taking of the deposition was concluded.)

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

———————————x

DEPUY MITEK INC., a Massachusetts Corporation, Plaintiff, vs. ANTHREX, INC., a Delaware Corporation, and PEARSALLS LIMITED, a Private Limited Company of the United Kingdom, Defendants.

: Civil Action No. 04-12457

———————————x

ACKNOWLEDGMENT OF DEPONENT

I, DR. NORM V. GITIS, do hereby acknowledge that I have read and examined pages 5 through 312 of the transcript of my deposition taken on Wednesday, June 21, 2006, and that:

(Check appropriate box):

( ) the same is a true, correct and complete transcription of the answers given by me to the questions therein recorded.

( ) except for the changes noted in the attached errata sheet, the same is a true, correct and complete transcription of the answers given by me to the questions therein recorded.

_____ DATE

_____ SIGNATURE

Pearsalls

Pearsalls Limited
Tancred Street, Taunton,
Somerset, TA1 1RY, England

Tel. +44 (0)1823 253198
Fax. +44 (0)1823 336824
Email. sutures@pearsalls.co.uk
www.pearsalls.co.uk

Mr Salvadore Tamburo
Dickstein Shapiro Morin & Oshinsky LLP
2101 L Street NW
Washington DC 20037
USA

17 February 2006

SAMPLES
NO COMMERCIAL VALUE

These samples are for demonstration purposes only:

	Pearsalls Braided Fibrewire			
Qty	**Metres**	**USP**	**Finish**	**Batch No**
1	20	2	Coated	28893
1	20	2	Uncoated	28893

Value for Customs: £10
Despatched by: DHL 412 0897 546

Certified Correct
pp Pearsalls Limited

D L Lawson
Managing Director

Confidential

PR 08458

DHL EXPRESS

Shipment Air Waybill

412 0897 546

Charge to ☐ Shipper ☐ Receiver ☐ 3rd party

Payer Account No.

Shipment Insurance see reverse

☐ Yes

Shipper's account number

Contact name

Shipper's reference (up to 32 characters but only first 12 will be shown on invoice)

SAMPLES

Company name

Address

Postcode/Zip Code (required)

Phone, Fax or E-mail (required)

DICKSTEIN SHAPIRO + CORR LLP

2101 L STREET NW

WASHINGTON DC

Country

USA

Total number of packages: 1

Total Weight: 5.00 kg

Dimensions in cm: Pieces, Length, Width, Height

Give content and quantity

SAMPLES FOR TESTING

Dutiable shipments only (WPX) (Customs Requirement)

Attach the original and four copies of a Proforma or Commercial invoice

Shipper's VAT/GST number: 362 39 59 89

Receiver's VAT/GST or Shipper's EIN/SSN

Declared Value for Customs as on commercial/proforma invoice

Harmonised Commodity Code if applicable

TYPE OF EXPORT ☐ Permanent ☐ Repair / Return ☐ Temporary

Destination duties/taxes (if left blank receiver pays duties/taxes)

☐ Receiver ☐ Shipper ☐ Other

Shipper's Declaration

Unless otherwise agreed in writing, I/we agree that DHL's terms and Conditions of Carriage are the terms of the contract between me/us and DHL and (1) such Terms and Conditions and, where applicable, the Warsaw Convention limits and/or excludes DHL's liability for loss, damage or delay and (2) this shipment does not contain cash or dangerous goods (see reverse).

Signature

Date 17 AUG 04

PT02/05 F15GBMP

PR 08460

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

Civil Action No. 04-12457 PBS

DEPUY MITEK, INC., a Massachusetts Corporation,

Plaintiff,

v.

ARTHREX, INC., a Delaware Corporation

Defendant.

Videotaped Deposition of DEBI PRASAD MUKHERJEE

- VOLUME TWO -

Washington, DC

Wednesday, June 14, 2006

The videotaped deposition of DEBI PRASAD MUKHERJEE, Volume Two, was held on Wednesday, June 14, 2006, commencing at 9:12 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, Northwest, Washington, DC, before Mary Ann Payonk, RDR, Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public.

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but -- and, you know, you measure the strength of the string whereas in bending, you do this way.
Q You do what way?
A And -- like you hold this and you bend. You know, the forces go perpendicular to the direction of the fiber. Now, nevertheless, this is what these people have done. They know what technique they used here.
Q Okay.
A I'm not really familiar with their equipment, so -- their setup, so this person, Norm Gitis, is the expert.
Q Okay.
A He's the person can answer all your questions, how it was done and what tests that it was used.
Q Okay. Now, the -- the bending test you used, did you -- if I understand your testimony, you're saying a tension test, normally a specimen is loaded and you pull longitudinally on the specimen, is that right?
A Right.
Q And you were saying a bending test, normally you --
A You --

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Q -- perpendicular --
A -- bend it.
Q Transverse wise.
Do you know which way the specimen in the pliability test that Dr. Gitis performed was loaded?
A I think it is a tensile test. That's what he did.
Q You think he did a tensile test?
A That's my assumption. Norm Gitis is a better person to tell you.
Q In a tension test, I think you said you pull longitudinally one direction. But don't you normally do it in two directions?
A No. Normally you do one direction.
Q In a tension test?
A Yes.
Q Why -- why did -- is -- why would -- why is -- why is it -- why do you do a tension test here then and call it a pliability test?
MR. TAMBURO: Objection. The witness already stated that he did not perform the tests and he doesn't know the details about the tests and your best person to ask is the person who did the tests, the expert who did the tests, Norm Gitis. You're welcome to ask your -- ask your questions, but he's already told you he doesn't know.
A This says -- in fact, you see the reference was given.
BY MR. BONELLA:
Q Right.
A The Rodeheaver, they followed the Rodeheaver's test. There's a reference to Rodeheaver, and it's a published paper and the procedure is used according to his paper. Again, Norman Gitis is the person to answer your question.
Q Can you tell me why it was okay to use this test for determine -- I'm sorry.
Can you tell me why it was okay to use the pliability tests that Dr. Gitis used to determine pliability for FiberWire?
MR. TAMBURO: Same objection. The witness is not an expert in these test procedures, and he's already told you that the person to speak with is Norm Gitis. To the extent you know the answer, you can answer.
A I answered your question before.
BY MR. BONELLA:
Q What is your answer?
A That I do not know.
Q Okay. Did you approve the pliability

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tests that he -- that he did? I'm sorry, I'll ask you that question. Did you approve the pliability tests that Dr. Gitis did before he did it?
MR. TAMBURO: Objection, vague.
A He's the authority. He decided on it and -- and we just did the -- we didn't measure pliability, all right? That is the extent of conversation I had. He decided the procedure and the technique.
(Exhibit No. 363 was marked.)
BY MR. BONELLA:
Q Okay. I'll show you DePuy Mitek Exhibit 363 -- it's Bates numbers CETR42 through 47 -- and ask you if you recognize the e-mail chain in Exhibit 363.
A Yes, I do.
Q Okay. And is the DMUKH@earthlink.net address, is that your e-mail address?
A KHE. There's no E there. DMUKHE at Earthlink.
Q What is your e-mail address?
A DMUKHE, but it doesn't have an E there.
Q Doesn't have an E? Right.
A Because there is no E there.
Q Right. Well, what is your e-mail? Your

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about those phone calls.
A That's just general discussion but not any specific recommendation on my part. That much I can summarize. I don't remember a specifics.
Q Okay. Have you told me everything you can remember about those phone calls?
A Yes, I have told you that.
Q If you go back to Exhibit 20, to your report --
A Yes, page 20.
Q Exhibit 240. Go to Exhibit 20, the CTR testing.
A 20.
Q And go to the pliability test again.
A That's page 2?
Q Starts on the bottom of page 2.
A Okay.
Q Doesn't the test that was performed for pliability test that CTR -- CETR did assume that the compressive and tensile module -- moduli for the specimen tested are equal?
MR. TAMBURO: Objection. The witness said he's not familiar with the -- specifically familiar with these procedures and the best person to ask is the expert who did the test. But to the extent you

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know the answer, go ahead and answer.
A Again I repeat my answer as before. Norman Gitis is the person did all of this, so I do not know.
BY MR. BONELLA:
Q Do you know whether the pliability tests that CETR did assumes that the specimen was a monolithic structure?
MR. TAMBURO: Same objection.
A The same answer. I do not know.
BY MR. BONELLA:
Q For a multifilament, isn't the bending strength or stiffness a function of the number of fibers?
A I do not know the answer.
Q For a multifilament, isn't the bending strength or stiffness a function of the individual fiber diameter?
A I do not know the specific answer.
Q Did you review any of Dr. Brookstein's exhibits which describe bending testing or stiffness testing of multifilament structures?
MR. TAMBURO: Objection to the extent it assumes facts.
A I have, but I don't remember the

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specifics.
BY MR. BONELLA:
Q Okay. If you could go to Exhibit DD of Exhibit 360, the rebuttal expert report of Dr. Brookstein, please. Did -- did you review that document? It's in Exhibit DD, The Mechanics of Elastic Performance of Textile Materials.
A Yes.
Q You did?
And what -- what -- did -- do you have any opinion about how multifilament structures should be tested for bending strength based on that document?
A Sir, this is beyond me. I didn't know the -- all the math, but all it did, the gist of this material, this -- this paper is -- again, I don't remember. Unless I read it again, I can't give you the answer.
Q So sitting here today you can't remember any opinions you formed based on Exhibit D -- DD to Dr. Brookstein's rebuttal report, The Mechanics of Elastic Performance of Textile Materials?
A No, because it's very complex and it's beyond me to understand.
Q Okay. Doesn't the fiber-to-fiber mobility --

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A Where are you now?
Q I'm not -- I'm just asking a question.
A Oh, okay. Which document?
Q So I'm done with that.
A Oh, oh, okay.
Q Doesn't the fiber-to-fiber mobility of a multifilament structure affect its bending strength?
MR. TAMBURO: Objection, vague.
A I don't want to speculate. It may.
BY MR. BONELLA:
Q You don't know?
A No.
Q Does fiber-to-fiber mobility in a multifilament structure affect the structure's moment of inertia?
MR. TAMBURO: Objection, vague.
A I cannot say for sure.
BY MR. BONELLA:
Q Does the multifilament structure -- for multifilament structure is the stiffness or pliability a function of the individual fiber moduli?
MR. TAMBURO: Objection, vague.
A It may be, but it -- in a very complex manner. I -- and I am -- I cannot give you any specific answer to that.

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6?
MR. TAMBURO: Objection. The witness did not do these tests so he already said he doesn't know.
A I -- I -- I think I answered your question. I cannot answer any more.
MR. BONELLA: You need to answer my question.
MR. TAMBURO: Objection. He already did.
BY MR. BONELLA:
Q Sample 2 and sample 6, do you know of any variations between sample 2 in table 1 and sample 6 in table 1?
A No, I don't.
Q Okay. So if you don't know any variations in the samples between sample 2 and you don't know of any variations in the procedures between sample 2 and sample 6, why isn't it fair to compare the values in sample 2 and sample 6?
MR. TAMBURO: Objection. You're unfairly trying to manipulate the testimony here and it's -- it's -- it's -- it's -- it's not fair. It's not fair. He's already told you that Norm Gitis is the person that did the tests, and he doesn't know if there's any differences between the samples. He already told you it's a possibility. That's why it wouldn't be fair to

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compare the two. And you're asking him -- you -- you're -- you're establishing a fact that there is no difference when he tells you that there -- there -- there -- there could be a difference and he's not sure of what the difference is. That's unfair. And he already gave you have the answer.
If you know the answer to his question, go ahead and answer.
THE WITNESS: I don't know the answer to the question.
MR. BONELLA: Okay. I'd appreciate it if you keep your speaking objection to a minimum.
MR. TAMBURO: I --
MR. BONELLA: That was a speech. And if you have an objection, state it. You're wasting my time on the record, and --
MR. TAMBURO: I would love to -- I would love to --
MR. BONELLA: -- I'm going to ask for more time.
MR. TAMBURO: I would love to give a short objection, but they don't seem to work with you.
BY MR. BONELLA:
Q The -- did you ask Dr. Gitis whether there was any variations in the procedures or the samples

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that he tested for the pliability test data?
A I did not, and I left to his expertise.
Q Okay. The knot slippage strength tests, the next set of tests.
A Yeah.
Q Okay?
A I see it.
Q Can you determine -- do you see the curves on page 6 that were obtained, force versus time?
A Page 6, yeah.
Q Can you determine from those tests a bending stiffness?
MR. TAMBURO: Objection.
A Again --
MR. TAMBURO: Objection, vague.
A Again, Norman Gitis is expert. He knows. I do not know.
BY MR. BONELLA:
Q You don't know? See the slope of the curves in the beginning in the force versus time graph on page 6?
A Yes.
Q Okay. Can you determine a modulus from the slope of those curves?
MR. TAMBURO: Objection, vague.

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A Again, Norman Gitis is the expert. He knows the answer.
BY MR. BONELLA:
Q You don't know?
A I do not know.
Q Did you consider in your analysis in your opinions whether stiffness can be determined from the test that was done in the knot slippage strength test by Dr. Gitis?
A Again, Dr. Gitis is expert. He knows. I do not know the answer.
Q So you didn't consider that?
A I -- I did not -- not know.
Q Okay, okay. You -- what's your understanding of -- going to the test data for the --
A Which page?
Q Page 6, the knot strength data in table 2.
A 6, yes.
Q But before we do that, did you see the curves at the top?
A On the --
Q In the -- in the graph.
A Force -- force versus time?
Q Yes.
A Yes.

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Q Not all eight sample curves are on there. Do you see that? For the coated and uncoated, it shows looks like four sample curves for the uncoated and three for the coated. I'm sorry, maybe it's three for the uncoated and --
A That's what I was looking --
Q Sorry, sorry.
A -- if you let me read this. That's what I was doing. Three for the uncoated.
Q And three for the coated?
A Right.
Q Okay. He tested eight samples?
A Yes.
Q Okay. Did you see the curves for the other five samples?
A Again, he reported the data. I did not see anything beyond what's in here.
Q Okay. For the knot strength at knot failure, do you see the coated and uncoated? See that?
A Yes.
Q Sample number 1, the uncoated, failed at 4.09, and the coated failed at 3.06, right?
A Knot failure? Yes.
Q Okay. So the -- sample number 1, the

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uncoated, had a higher knot strength according to that test?
A Again, I cannot make any comments on individual data. Has to be the average and the statistical analysis of the data. And again, Norm Gitis can explain these questions that you are asking to me. I do not know the answer.
Q Can you explain why sample -- see sample number 1? The uncoated -- uncoated has a higher value than the coated. Do you see that?
A Yes.
Q For knot failure. See that?
A Sample number 1?
Q Right.
A Yes. The uncoated is higher than the coated?
Q That's what the number looks like.
A Okay.
Q That number of 4.09 is higher than --
A I just want to make sure that's what you're referring to.
Q Right.
A Okay?
Q Okay. Now, if you go down and you see sample number 3.

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A Yes.
Q Sample number 3, the coated number, is 3.15 at failure and the uncoated is 2.42. Do you see that?
A Yes, I do.
Q So for sample number one, the uncoated failed at a higher value -- value, and for sample number 3, the coated failed at a higher value. See that?
A I see.
Q How do you explain that?
A I answered your question over and over again that I cannot answer the individual data. Norm Gitis is the person who can explain this. I only can see the averages. To my knowledge, that's the way to look at it, not individual data like you're doing.
Q Okay. It -- it's your opinion -- is it your opinion that the coating on FiberWire decreases the knot strength?
MR. TAMBURO: Objection, vague. Are we going by the same definition of knot strength as yesterday?
MR. BONELLA: The knot strength as reported in table 2 of Dr. Gitis' report.
A I have to look at the statistical analysis

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of these variations. Uncoated variations are a little higher than the coated so I'm not sure what the statistical averages showed. So again, Norm can answer the question.
BY MR. BONELLA:
Q Do you have an opinion of whether the coating caused the knot strength to either increase or decrease?
A No, I don't, because it -- it varies with the materials and everything. So I don't have a general opinion, no.
Q No, I'm -- not general opinion, I'm talking about the -- as -- based on the testing that's reported in table 2, do you have an opinion whether the -- the coating on FiberWire caused the knot strength to either increase or decrease as reported in table 2?
A Again, I have to look at the statistical analysis of these data. And again, Norm will -- will tell you that. And I'm not -- I am not really sure that I can answer your question. I cannot.
Q Cannot? Okay. Next test is the knot rundown test.
A Which page?
Q Page 7 of Exhibit 20. The CETR report.

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A Page 7, yes.
Q Okay. Are you familiar with how this test was performed?
A Not really. He's the expert. Norm Gitis is expert. He did what is procedure he used.
Q And the tests before that, the knot slippage test, were you -- are you familiar with how those tests were done?
A No.
Q Okay. The knot rundown test data that's in table 3 on page 8, do you see that?
A Okay, yes, I do.
Q Do you have an opinion as to whether the coat -- how the -- whether the coating affects -- I'm sorry, I'll ask the -- reask that question.
Do you have an opinion as to whether the FiberWire's coating affects the knot rundown --
MR. TAMBURO: Objection, vague.
BY MR. BONELLA:
Q -- based on table 3?
A No, I do not.
Q Okay. Did you ever see any of the graphs, any graph other than what's reported -- I'm sorry.
Did you ever see any knot rundown curves other than the ones reported in figure 8 that

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Dr. Gitis did?
A No, I did -- did not.
Q Can you explain why sample 1, coated suture, had a knot rundown of 0.28 in the table?
Yeah, sample 1 had a knot rundown of 0.28 and sample 7 -- I'm sorry.
Can you explain why the coated, sample 1, had a rundown force of 0.28 and the uncoated, sample 7, had a rundown force of 0.28, which are the same?
A Same answer as before. I -- we -- I cannot explain any of the individual data. You have to ask Norm Gitis for the answer. I do not know.
Q The next test is a friction test. Are you familiar with how that test was performed?
A Again, Norm is the expert. That's what he did. I do not know.
Q Okay. Let me back up to the test before that again, the rundown --
A Where are you now?
Q I'm sorry, the rundown test.
A Page 7?
Q Still on page 8.
A Page 8.
Q Did you consider in your analysis whether the bending strength or pliability of the uncoated and

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coated sutures that Dr. Gitis tested could be determined from the knot rundown test that he did?
A No. Again, Norm Gitis is the expert. He knows the answer. I do not.
Q If the -- if the knot rundown tests and the knot slippage tests show that the --
A Now, knot rundown is page 8.
Q Right.
A And knot slippage is page 6?
Q Right.
If the knot slippage and knot rundown tests show that the coated suture is stiffer than the uncoated suture, how would you explain that?
A Again, Norm Gitis is -- is the expert. He can explain the data.
Q Are you an expert in explaining the results of this data that Dr. Gitis did and how it relates to FiberWire's coating?
A Not really.
Q Okay. In the friction test that he did, you see table 4, the friction test?
A Page?
Q Page 11 of CETR report.
A Okay.
Q See the friction data?

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A Yes.
Q Okay. See how the coated had an average of .09 and the uncoated had an average of 0.16? Do you see that?
A Sample number -- which one you talking about?
Q No, average.
A Average .009 and .014? Is that the one?
Q Sorry. I'm in the coefficient of friction, table 4, test at the top.
A I will check it. Okay.
Q Okay? See how the coated had a average of 0.09?
A Right, yes.
Q And the uncoated had 0.16?
A Right.
Q Have you seen any data to put other data of other sutures of what their coefficient of frictions were?
MR. TAMBURO: Objection, vague.
A I don't remember. I've seen my own eyes working suture but not -- I don't remember.
BY MR. BONELLA:
Q Do you remember what values you saw in your experience for coefficient of frictions for

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sutures?
A No, I don't.
Q Okay. Did you do any analysis of any of the CETR data to see how it compares to sutures in general to determine whether -- any effects on the material?
A No, I did not.
Q Okay. The chatter data on page 11 of the report that's CETR report, page 11, the chatter data.
A Yeah. Page 11. 16, 14 -- yeah.
Q Do you know how that data was determined?
A No. Again, Norm Gitis the person who answer the question.
Q Okay. See how sample 6 had a value of 0.012?
A 6, yeah.
Q For the coated?
A Yeah.
Q And for sample 6, the uncoated value was 0.011?
A Yes.
Q Are they about the same?
A Again --
MR. TAMBURO: Objection, vague.
A -- Norm Gitis can answer that question. I

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cannot.
BY MR. BONELLA:
Q You can't answer the question of 0.12 and 0.011 are about the same?
MR. TAMBURO: Objection, vague.
A No, I cannot.
BY MR. BONELLA:
Q You cannot?
Sample 5, uncoated, had a value of 0.012, right?
A Sample 5? Yes.
Q Uncoated. So sample 5, the value, uncoated, was the same as sample 6 value, coated. Do you see that?
A Yeah.
Q Can you explain why that's true?
A Again, the sample-to-sample variation, Norm Gitis will be able to explain why it is.
Q Can you -- do you have an opinion as to how coating affects the -- let me back up.
Based on table 5, did you have any -- do you have any opinions about how the coating affects the chatter of a suture -- of the FiberWire suture?
A No, but if you look at 16, where the data were compared statistically, that's where I make my --

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I made my opinion.
If you look at the stiffness, all the properties, coated and uncoated, differences, I -- I just wanted to see whether different or not. And I saw coated is different from uncoated. That much, I did. But other than that, I haven't done anything else. And Norm again who is the person to explain more about the individual data point as well as averages.
Q So you started by saying "no" to my question, so do you have any opinions about how the coating affects the chatter of a suture, of the FiberWire suture?
A The answer is no.
Q Okay. Next test is a tissue drag test. Do you know how that was performed?
A No.
Q Okay.
A Now, what page is that?
Q Page 12.
A Page 12. Yeah.
Q Did -- have you seen any curves other than what's shown in figure 13 for the tissue drag test results?
A No.

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Q In the drag force table, see the static columns on the left?
A Yes.
Q On the left-hand side, sample number 1, the coated suture had a static value drag force of 1.10. See that?
A Yes.
Q Number 5, sample number 5, uncoated, had a value of 1.10. Do you see that?
A Yes.
Q Can you explain why sample number 1, coated suture, and sample number 5, uncoated suture, have the same static value of drag force?
A Again, Norm Gitis can explain. I cannot.
Q Do you have any opinions about how the coating on FiberWire affects the drag force?
A No.
Q Next page is visual samples, pictures.
A Yes.
Q Page 14.
A Yes.
Q It shows four pictures on page 14. It should be Exhibit C to your report.
A 14 and 15, yes.
Q See the four pictures?

-----Original Message-----
From: Tamburo, Salvatore [mailto:TamburoS@dsmo.com]
Sent: Wednesday, May 24, 2006 3:30 PM
To: Bonella, Michael J. (Woodcock Washburn)
Cc: Saber, Charles
Subject: DePuy Mitek v. Arthrex - Letter dated May 23, 2006

Mike:

Responsive to your letter dated May 23, 2006 to Chuck, once again, you have chosen to willfully misread our letter. Although you are entitled to nothing, we offered to respond to an interrogatory to Pearsalls in lieu of Pearsalls depositions. We agreed to do one or the other. We did not offer an interrogatory in addition to Pearsalls depositions, nor did we offer to respond to an interrogatory to Arthrex.

If you are willing to proceed by interrogatory to Pearsalls in lieu of depositions, please confirm this in writing; otherwise, we object to the interrogatory.

If we receive your confirmation by May 26, 2006, we will respond to the interrogatory to Pearsalls by June 9, 2006.

- Sal

Sal Tamburo
Dickstein Shapiro Morin & Oshinsky LLP
2101 L Street NW
Washington, DC 20037
phone: (202) 822-5164
fax: (202) 887-0689
email: TamburoS@dsmo.com

To reply to our email administrator directly, send an email to postmaster@dsmo.com

Dickstein Shapiro Morin & Oshinsky LLP
http://www.DicksteinShapiro.com

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ATLANTA • PHILADELPHIA • SEATTLE

PHILADELPHIA OFFICE
One Liberty Place, 46th Floor
Philadelphia, PA 19103
215-568-3100
Fax: 215-568-3439

May 25, 2006

MICHAEL J. BONELLA
PHILADELPHIA OFFICE
215-564-8987
bonella@woodcock.com

Via Email
Salvatore Tamburo, Esq.
Dickstein Shapiro Morin &
Oshinsky LLP
2101 L Street, N.W.
Washington, D.C. 20037

Re: DePuy Mitek, Inc. v. Arthrex, Inc. & Pearsalls, Inc.
Case No. 04-12457 PBS

Dear Sal:

Thank you for your May 24, 2006 communication regarding the interrogatories and fact depositions. We are disappointed that you have refused to answer the interrogatories unless we agree to forgo fact depositions. As we had indicated, answering the depositions may eliminate the need for any Pearsalls' fact depositions and would likely reduce the number of depositions because it would identify the relevance of any witnesses. As a practical matter, I am not sure how you expect us to identify who to depose without answering the interrogatory, but we are open to suggestions.

Although two months have passed since Dr. Gitis' report was served, neither Arthrex nor Pearsalls has supplemented its initial disclosures to identify any witnesses that they may bring to trial to authenticate the samples tested by Dr. Gitis and how they were manufactured. Please let us know by tomorrow whether Pearsalls and Arthrex will be supplementing their Rule 26 initial disclosures, and if so, when we can expect to receive their supplementations.

In any event, please identify the Pearsalls' witnesses who have first hand knowledge of how the coated and uncoated samples that were tested by Dr. Gitis were manufactured and the date and location of their potential depositions. We would serve subpoenas, but we do not know whom to depose.

As Dr. Brookstein may be supplementing his report based on the Pearsalls' fact depositions, we propose that we conduct his deposition after the Pearsalls' fact depositions. This will likely require moving his deposition to July. In any event, based on your recent

WOODCOCK WASHBURN

communication regarding scheduling, his deposition might have to be scheduled in July based on a lack of available dates. But I will address scheduling in another communication.

Sincerely,

Michael J. Bonella

LEXSEE 2005 U.S. DIST. LEXIS 42134

SHERIE WHITE, Plaintiff, v. CINEMARK USA, INC., dba CINEMARK MOVIES 8, ** Defendants.

** The caption is amended to reflect the dismissal of Does 1 through 10 (Status (Pretrial Scheduling) Order at 2) and Yuba Cinema Associates, Ltd. (Order July 2, 2004).

No. 2:04-cv-397-GEB-CMK

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF CALIFORNIA

2005 U.S. Dist. LEXIS 42134

August 3, 2005, Decided
August 4, 2005, Filed

PRIOR HISTORY: *White v. Cinemark USA, Inc., 2005 U.S. Dist. LEXIS 41780 (E.D. Cal., Apr. 26, 2005)*

COUNSEL: [*1] For Sherie White, Plaintiff: Lynn Hubbard, Law Offices of Lynn Hubbard III, Chico, CA.

For Cinemark USA Inc, Doing business as Cinemark Movies 8, Defendant: Heather Burror, Richard Cortez, Jr, Roland M. Juarez, Akin Gump Strauss Hauer and Feld LLP, San Francisco, CA.

JUDGES: GARLAND E. BURRELL, JR., United States District Judge.

OPINIONBY: GARLAND E. BURRELL, JR.

OPINION:

ORDER *

* This matter was deemed appropriate for adjudication without a hearing pursuant to *Local Rule 78-230(h)*.

Plaintiff moves for summary judgment on her claims under the California Unruh Civil Rights Act and the California Disabled Persons Act. *Cal. Civ. Code § § 51-53, 54-55.2*. Plaintiff also moves for summary judgment on her claim under *section 19955 of the California Health & Safety Code*. Plaintiff, a quadriplegic, alleges that she encountered barriers at the Defendant's Yuba City movie theater ("Theater"), which she visited on January 4, 2004.

Defendant separately moves for summary judgment on Plaintiff's claim under [*2] the Americans with Disabilities Act, *42 U.S.C. § § 12101-12213*, as well as all of her state law claims. In addition, Defendant moves for terminating sanctions or, in the alternative, for evidence preclusion sanctions under *Federal Rule of Civil Procedure 37(d)* and the court's inherent power. n1 Plaintiff opposes Defendant's motion for sanctions and filed a counter-motion for sanctions under *Rule 16(f)*.

n1 Unless otherwise indicated, all references to Rules are to the Federal Rules of Civil Procedure.

DISCUSSION

I. Cross-Motions for Sanctions

Defendant argues that terminating sanctions are appropriate because Plaintiff failed to appear at her properly noticed deposition, and Plaintiff's counsel wrongfully prevented Plaintiff's experts from appearing at their properly noticed depositions. Alternatively, Defendant seeks a sanction precluding the testimony of Plaintiff and her two experts. n2 Plaintiff responds [*3] that Defendant's motion is an untimely discovery motion that is barred because the Status (Pretrial Scheduling) Order ("Scheduling Order"), as amended, called for all discovery to be completed by April 25, 2005. In addition, Plaintiff seeks monetary sanctions from Defendant under *Rule 16(f)* in the amount of $ 11,375.00, as well as an order that Defendant's counsel reimburse Defendant $

11,075.50 for the costs incurred preparing its motion for sanctions.

n2 Defendant also seeks $ 11,075.50 in costs incurred preparing its motion for sanctions should sanctions be awarded.

The first issue is whether Defendant may bring a motion for terminating sanctions under *Rule 37(d)* after the April 25, 2005, discovery "completion" date. (Feb. 18, 2005, Order at 2.) The Scheduling Order explains that "'completed' means that all discovery shall have been conducted so that all depositions have been taken and any disputes relative to discovery shall have been resolved by appropriate orders, if necessary, and where discovery has been [*4] ordered, the order has been complied with or, alternatively, the time allowed for such compliance shall have expired." (Scheduling Order at 2-3.) In addition, the Scheduling Order warns that "[a] party conducting discovery near the discovery 'completion' date runs the risk of losing the opportunity to have a jurist resolve discovery motions pursuant to the Local Rules." (Id. at 3 n.2.) *Local Rule 72-302(c)(1)*, which is cited in the Scheduling Order, states that the magistrate judge hears motions for sanctions under *Rule 37*. Thus, motions for sanctions under *Rule 37* should normally be brought before the magistrate judge within the time allotted for completion of discovery in the *Rule 16* scheduling order. *Freeman v. Allstate Life Ins. Co., 253 F.3d 533, 537 (9th Cir. 2001)* (upholding the requirement that discovery disputes be timely prosecuted before the magistrate judge, as required by the *Rule 16* scheduling order and *Local Rule 72-302(c)*).

However, Plaintiff's attempt to use the Scheduling Order as both a sword (by preventing the deposition of Plaintiff and her experts) and a shield (by preventing sanctions for discovery violations that occurred immediately [*5] before the "completion" of discovery) is improper. See *Payne v. Exxon Corp., 121 F.3d 503, 508 (9th Cir. 1997)* (rejecting the argument that "the district court erred by considering all of [Plaintiff's] discovery misconduct in connection with its decision to dismiss, because the time to challenge [Plaintiff's] responses to [Defendant's] first round of discovery 'had long since passed.'"). *Rule 1* requires that *Rule 16* and *Rule 37* "be construed and administered to secure the just, speedy, and inexpensive determination of every action." Further, "[l]itigants are expected to act in good faith in complying with their discovery obligations, and [Plaintiff's] reliance on [her] own delay to justify refusing to produce [her experts or to attend her own properly noticed deposition] was anything but good faith." *Johnson v. J.B. Hunt Transp., Inc., 280 F.3d 1125, 1132 (7th Cir. 2002).* Therefore, Plaintiff's argument that *Rule 16* insulates her from sanctions because the time for completing discovery has lapsed is erroneous and her cross-motion for *Rule 16(f)* sanctions is denied.

A. Plaintiff's Experts

Defendant did not heed footnote 2 of the [*6] Status Order and waited until the final two weeks of discovery to notice the deposition of Plaintiff's two expert witnesses. Defendant's delayed effort to depose Plaintiff's expert witnesses does not justify use of the severe sanction of either dismissal or evidence preclusion. n3

n3 Likewise, Defendant's claim that in April 2005 it "learned that Plaintiff's disclosures for one of the experts included only a post office box, rendering service of the subpoena much more costly and burdensome" is unpersuasive since Defendant should have addressed this defect closer to the time when the expert report was disclosed in January 2005.

B. Plaintiff

Defendant first noticed Plaintiff's deposition on December 9, 2004, setting the deposition for February 1, 2005. (Burror Decl. Supp. Def.'s Mot. Sanctions P 3.) Plaintiff twice requested to reschedule the deposition, and Defendant accommodated Plaintiff on each occasion. (Id. PP 3-4.) Plaintiff's counsel unilaterally took the third-noticed deposition off-calendar, [*7] but did not provide an alternative date to hold the deposition. (Id. P 5.) Upon meeting and conferring with Plaintiff's counsel, Plaintiff's deposition was rescheduled for April 11, 2005. (Id. P 6.) Plaintiff did not appear. (Id. P 7.) Afterward, Plaintiff's counsel agreed to produce Plaintiff for a deposition on April 25, 2005 -- the last day available for discovery. (Id. P 8.) However, once the magistrate judge denied Defendant's motion to compel the appearance of Plaintiff's experts, Plaintiff, and a third-party witness, Plaintiff refused to appear, claiming that she could not arrange for transportation to the noticed location for the deposition. (Id.)

Terminating sanctions requires a showing of willful disobedience, fault, or bad faith. *In re Exxon Valdez, 102 F.3d 429, 432 (9th Cir. 1996)*. Disobedience, fault, or bad faith exists where "disobedient conduct [is] not shown to be outside the control of the litigant." *Fjelstad v. Am. Honda Motor Co., 762 F.2d 1334, 1341 (9th Cir. 1990)*, quoted in *Henry v. Gill Indus., Inc., 983 F.2d 943, 948 (9th Cir. 1993)*. Defendant fails to identify the ground for a finding of [*8] willful disobedience, fault, or bad faith. Indeed, Defendant does not identify this necessary showing as an element of a case-terminating

sanction. (Def.'s Br. Supp. Def.'s Mot. Sanctions at 8.) Therefore, Defendant is not entitled to terminating sanctions under *Rule 37* since this element will not be raised and addressed *sua sponte.* Furthermore, precluding Plaintiff from testifying and striking her declarations serves as a *de facto* terminating sanction, which requires a specific finding of willful disobedience, fault, or bad faith. *United States for Use & Ben. of Wiltec Guam, Inc. v. Kahaluu Constr. Co., Inc., 857 F.2d 600, 602-03, 603 n.5 (9th Cir. 1988).* Therefore, Defendant's motion for terminating sanctions or evidence preclusion is denied, as is Defendant's request for the costs it incurred in preparing its motion for sanctions.

II. Defendant's Objection to Card's Declaration

Defendant moves to strike the declaration of Joseph Card (Plaintiff's expert), which Plaintiff filed in support of her motion for summary judgment. Defedant argues, *inter alia*, that Card's declaration violates *Rule 26* because Card's expert report analyzed the Theater [*9] under the 2001 California Building Code ("CBC"), but his declaration analyzed the Theater under the 1984 CBC. n4 Plaintiff characterizes Card's declaration as a supplement to his January 21, 2005, expert report, or a surrebuttal to Kim Blackseth's (Defendant's expert) rebuttal to Card's January 21, 2005, expert report. (Pl.'s Reply Br. Supp. Pl.'s Mot. Summ. J. at 2-3.)

> n4 Plaintiff also objects to Card's analysis of the Theater under the Americans with Disability Act Accessibility Guidelines ("ADAAG") because his analysis does not evaluate the Theater under the ADA's "readily achievable" standard. This argument, however, is not a basis for striking Card's declaration as an improper expert report.

Rule 26(e)(1) imposes a duty to supplement an expert's report if (1) the court so orders, (2) the party learns that the earlier information is inaccurate or incomplete, or (3) answers to discovery requests are inaccurate or incomplete. A party may not use a "non-opinion" as a placeholder to spring a "supplemental opinion" [*10] in the eleventh hour that squarely addresses the issues in a case. *Keener v. United States, 181 F.R.D. 639, 641 (D. Mont. 1998).* As concerning potential violations of the CBC, Card's initial report was a "non-opinion" because it analyzed the Theater under an inapplicable standard. Cf. id. n5 Indeed, Card negates the need to supplement his expert report by declaring that the information in his January 21, 2005, report is neither inaccurate nor incomplete. (Card Decl. P 7.) Therefore, the portion of Card's declaration discussing alleged violations of the 1984 CBC is not a supplement to his January 21, 2005, expert report under *Rule 26(e)(1).* Further, Card's declaration cannot be characterized as a valid rebuttal to Blackseth's rebuttal because it was disclosed after the time allotted for rebuttal reports had expired. (Feb. 18, 2005, Order at 2; Blackseth Decl. P 6.) In addition, *Rule 26(a)(2)(C)* does not provide for a surrebuttal report.

> n5 Plaintiff argues that the 2001 CBC provisions apply because "barrier removal under federal law . . . is an alteration under state law, and triggers compliance with the current version of the CBC." (Pl.'s Br. Opp'n Def.'s Mot. Summ. J. at 16.) This argument, however, does not justify subjecting the Theater to the provisions of the 2001 CBC *before* alterations are made to an existing facility. *Cal. Health & Saf. Code § 19959.*

[*11]

Since the portion of Card's declaration discussing alleged violations of the 1984 CBC at the Theater is neither a supplement to his January 21, 2005, expert report, nor a rebuttal under *Rule 26(a)(2)(C),* the declaration must be considered a separate expert report. See *Keener, 181 F.R.D. at 641-42.* As such, the portions of Card's declaration analyzing the Theater under the 1984 CBC are stricken because they were not submitted within the time allotted for expert reports set forth in the Scheduling Order. *Pickern v. Pier 1 Imports, Inc., 339 F. Supp. 2d 1081, 1088-89 (E.D. Cal. 2004).*

III. Plaintiff's Motion for Summary Judgment n6

> n6 "The standards applicable to motions for summary judgment are well known, see, e.g., *Rodgers v. County of Yolo, 889 F. Supp. 1284 (E.D. Cal. 1995),* and need not be repeated here." *Reitter v. City of Sacramento, 87 F. Supp. 2d 1040, 1042 (E.D. Cal. 2000).*

A. Plaintiff's Claims

Plaintiff moves for summary [*12] judgment on her claim under the California Unruh Civil Rights Act and the California Disabled Persons Act, arguing that Defendant violated the ADA and the CBC. *Title III of the ADA* prescribes: "No individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who owns . . . or operates a place of public accommodation." *42 U.S.C. § 12182(a).* For public accommodations constructed before 1993 ("existing

facilities"), discrimination includes "a failure to remove architectural barriers . . . where such removal is readily achievable." Id. *§ 12182(b)(2)(A)(iv)*. The ADAAG "'provide valuable guidance for determining whether an existing facility contains architectural barriers.'" *Pascuti v. New York Yankees, 87 F. Supp. 2d 221, 226 (S.D.N.Y. 1999)*, quoted in *D'Lil v. Stardust Vacation Club, 2001 U.S. Dist. LEXIS 23309, CIV-S-00-1496, 2001 WL 1825832, at *4 (E.D. Cal. Dec. 21, 2001)*.

Plaintiff tersely lists aspects of the Theater that allegedly violate the ADAAG. (Pl.'s Br. Supp. Pl.'s Mot. [*13] Summ. J. at 6-9.) While citing to violations of the ADAAG will prevent Defendant from obtaining summary judgment on Plaintiff's ADA claims, those violations, standing alone, do not "show that there is a genuine issue as to any material fact [such that Plaintiff] is entitled to judgment as a matter of law." *Fed. R. Civ. P. 56(c)*; *Access Now v. South Florida Stadium Corp., 161 F. Supp. 2d 1357, 1367 (S.D. Fla. 2001)*. Plaintiff's motion for summary judgment on her state law claims for violations of the ADA is denied because she has failed to demonstrate that the Theater "contained actual barriers that hindered her access." *Access Now, 161 F. Supp. 2d at 1367*, cited in *D'Lil, 2001 U.S. Dist. LEXIS 23309, 2001 WL 1825832, at *5*.

Alternatively, Plaintiff argues that she is entitled to relief under the Unruh Civil Rights Act because "she was 'denied full and equal' enjoyment and use of the [T]heater" in violation of the ADA's general non-discrimination language. (Pl.'s Br. Supp. Pl.'s Mot. Summ. J. at 11 (quoting *42 U.S.C. § 12182(a)*).) However, the ADA's general non-discrimination language must be [*14] considered in light of the regulatory context of the ADA, rather than evaluated in a vaccuum. *United States v. Nat'l Amusements, Inc., 180 F. Supp. 2d 251, 257 (D. Mass. 2001)*.

Plaintiff's motion for summary judgment on state law claims for violations of the CBC is denied because, as discussed above, those portions of Card's declaration analyzing the Theater under the 1984 CBC are stricken. Consequently, Plaintiff is denied summary judgment on these claims because she cannot establish a necessary element of these theories of liability. *Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986)*.

B. Defendant's Defenses

In the alternative, Plaintiff moves for summary judgment of Defendant's twenty-one affirmative defenses. To meet her initial burden of production under *Rule 56*, Plaintiff relies on Defendant's response to an interrogatory ("Question 12") requiring Defendant to identify, *inter alia*, all facts upon which it bases each of its affirmative defenses. (White Decl. Supp. Pl.'s Mot. Summ. J. P 43, Exh. B.) Defendant responded to Question 12 subject to an objection, which Magistrate Judge Kellison sustained. (March 25, 2005, Order at 5.) Pursuant [*15] to Magistrate Judge Kellison's order, Defendant supplemented its response to Question 12 by addressing its first, third, fourth, fifth, sixth, seventh, eighth, ninth, tenth, thirteenth, fourteenth, eighteenth, and twenty-first affirmative defenses. Thus, Plaintiff has failed to meet her initial burden of production under *Rule 56* as to Defendant's second, eleventh, twelfth, fifteenth, sixteenth, seventeenth, nineteenth, and twentieth affirmative defenses because she has not demonstrated the absence of a genuine issue of material fact. *Celotex Corp., 477 U.S. at 323* ("[A] party seeking summary judgment always bears the initial responsibility of '. . . identifying those portions of the pleadings, depositions, answers to interrogatories, and admission on file together with the affidavits, if any' which it believes demonstrate the absence of a genuine issue of material fact.") (quoting *Fed. R. Civ. P. 56(c)*). In addition, as to the affirmative defenses that Defendant addressed in its supplemental response to Question 12, Plaintiff fails to meet her initial burden of production under *Rule 56* because she has made no effort to show [*16] why she is entitled to summary judgment as a matter of law. Id. ("[A] party seeking summary judgment always bears the initial responsibility of informing the district court of the basis of the motion.").

For these reasons, Plaintiff's motion for summary judgment on Defendant's affirmative defenses is denied. Defendant withdraws the affirmative defenses of laches and statute of limitations in light of Plaintiff's acknowledgment that she is only seeking relief based on an alleged visit to the Theater on January 4, 2004. (Def.'s Br. Opp'n Pl.'s Mot. Summ. J. at 18 n.10.)

IV. Defendant's Motion for Summary Judgment

A. Standing

Although in its Notice of Motion for Summary Judgment Defendant states that Plaintiff's claim for relief under the Title III of the ADA fails for lack of standing, Defendant's brief is more narrow, since Defendant argues that Plaintiff is not entitled to injunctive relief under the ADA because there is no real or immediate threat of future injury. (Def.'s Br. Supp. Def.'s Mot for Summ. J. at 3-5.) n7 Defendant proffers two arguments to support its conclusion that Plaintiff lacks standing: (1) Plaintiff's visit to the Theater was a "fluke," and [*17] (2) there is no threat of future harm because within the upcoming months either Defendant will renovate the Theater, or Yuba City will condemn the Theater for construction of a public road. (Id.)

n7 Defendant argues in response to Plaintiff's motion for summary judgment that Plaintiff lacks standing to claim that the path from the accessible parking spaces crosses a route that vehicles travel without providing detectable warnings. (Def.'s Br. Opp'n Pl.'s Mot. Summ. J. at 14.) Defendant is granted summary adjudication on this issue because detectable warnings are designed to assist the visually impaired, and Plaintiff is not visually impaired. *Parr v. L&L Drive-Inn Rest., 96 F. Supp. 2d 1065, 1082 (D. Haw. 2000).*

Plaintiff counters Defendant's first argument by declaring that she regularly travels from her home in Corning to Sacramento along Highway 99, which takes her past the Theater. (White Decl. Opp'n Def.'s Mot. Summ. J. PP 7-8.) Plaintiff's declaration creates a genuine issue of material [*18] fact preventing summary judgment on the ground that Plaintiff's visit to the Theater was a "fluke."

Defendant's second argument "'[confuses] mootness with standing.'" *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 189, 120 S. Ct. 693, 145 L. Ed. 2d 610 (2000)*, quoted in *Adarand Constructors, Inc. v. Slater, 528 U.S. 216, 221-22, 120 S. Ct. 722, 145 L. Ed. 2d 650 (2000)* (per curiam). To prevail, Defendant must show that it is "absolutely clear that the alleged wrongful behavior could not reasonably be expected to reoccur." *Adarand, 528 U.S. at 222* (citation omitted). Neither Defendant's submission of a project application to Yuba City for a proposed renovation of the Theater, nor the prospect that Yuba City *may* condemn the Theater to construct a public road meets the lofty showing required by Adarand. Therefore, Defendant's motion for summary judgment on Plaintiff's ADA claim for lack of standing is denied.

In its reply brief, Defendant argues, for the first time, that Plaintiff did not suffer an injury in fact because Plaintiff was capable of actually accessing the Theater. (Def.'s Reply Br. Supp. Def.'s Mot for Summ. J. at 10.) Defendant's argument, however, [*19] incorrectly assumes that Plaintiff must be incapable of entering the Theater to sustain an injury in fact. Cf. *Boemio v. Love's Rest., 954 F. Supp. 204, 207 (S.D. Cal. 1997)* (analyzing the Unruh Civil Rights Act and concluding, "[i]f a finding that ultimate access could have been achieved provided a defense, the spirit of the law would be defeated.").

B. ADA

1. Barriers

Defendant asserts that the ADAAG do not apply to the Theater because it was built before January 1993. (Def.'s Br. Supp. Def.'s Mot. Summ. J. at 6.) Rather, Defendant contends, "the Theater is subject to the less burdensome readily achievable standard." (Id.) Although ADAAG violations are not conclusive proof of a barrier in existing facilities, they "'provide valuable guidance for determining whether an existing facility contains architectural barriers.'" *Pascuiti, 87 F. Supp. 2d at 226 (S.D.N.Y. 1999)*, quoted in *D'Lil, 2001 U.S. Dist. LEXIS 23309, 2001 WL 1825832, at *4*; see *28 C.F.R. § 36.304(g)* ("The requirements for barrier removal [in existing facilities] shall not be interpreted to *exceed* the standards for alterations in [the ADAAG].") [*20] (emphasis added). Thus, Defendant's motion for summary judgment on Plaintiff's ADA claim for want of architectural barriers is denied because Plaintiff has proffered sufficient evidence to create a genuine issue of material fact that such barriers exist. *Access Now, 161 F. Supp. 2d at 1367.*

2. Readily Achievable

Alternatively, Defendant argues that summary judgment is appropriate because the proposed barrier removal is not readily achievable. Readily achievable means "easily accomplishable and able to be carried out without much difficulty or expense." *28 C.F.R. § 36.304(a)*. "Whether a specific change is readily achievable 'is a fact intensive inquiry that will rarely be decided on summary judgment.'" *Colo. Cross Disability Coalition v. Hermanson Family Ltd. P'ship I, 264 F.3d 999, 1005 (10th Cir. 2001)*, quoted in *D'Lil, 2001 U.S. Dist. LEXIS 23309, 2001 WL 1825832, at *5* (listing ten "factors to be considered"). "[Plaintiff] bear[s] the initial burden of suggesting a method of barrier removal and proffering evidence that [her] suggested method meets the statutory definition of 'readily achievable.' If [Plaintiff] meet[s] [*21] this burden [Defendant] then bear[s] the ultimate burden of proving that the suggested method of removal is not readily achievable." *Pascuiti v. New York Yankees, 1999 U.S. Dist. LEXIS 18736, 98 CIV. 8186, 1999 WL 1102748 (S.D.N.Y. Dec. 6, 1999)*, cited in *Colo. Cross, 264 F.3d at 1005-06.*

Defendant asserts that Plaintiff fails to meet her initial burden of showing that proposed changes are readily achievable because "[she] only addresses . . . the cost of barrier removal." (Def.'s Br. Supp. Def.'s Mot. Summ. J. at 9.) Further, Defendant argues that Plaintiff "fails to offer evidence regarding the financial resources of the facility at issue, . . . fails to offer design plans under the readily achievable analysis relevant here[,] . . . [and] fails to provide any evidence that Yuba City would approve [her] proposed set of modifications." (Id.) However, Plaintiff submits with Card's declaration a "Cost Analysis letter" written to Plaintiff's counsel listing the projected costs of "removing architectural barriers per 1990 [ADA] and [CBC] Title 24 requirements," and organiz-

ing those costs in logical categories. (Card Decl. P 4, Exh. B.) Attached to this letter [*22] is a set of specific construction plans for the Theater addressing some of the alleged ADA violations at the Theater outlined in Card's declaration. (Id. at 2-13.) In addition, Plaintiff proffers the report of Harold Littlejohn, which analyzes Defendant's financial status and concludes that Defendant "has the financial capability of spending reasonable amounts on needed improvements to comply with ADA." (Burror Decl. Supp. Def.'s Mot. Summ. J. at P 8, Exh. F.)

Defendant rejoins that Plaintiff fails to provide financial analysis of the Theater, as opposed to Defendant's overall operations; however, this failure does not negate the Plaintiff's showing as to the other factors. Cf. *Colo. Cross, 264 F.3d at 1009* (holding that plaintiff's failure to provide specific construction plans, specific cost estimates, and the added nuance of the public accommodation being a historic building presented a "close case" for finding that plaintiff met his initial showing). Therefore, Defendant is denied summary judgment on Plaintiff's ADA claims on those barriers addressed in the Advanced Design Consultants' Accessibility Improvements Plan since a genuine issue of material fact [*23] exists on the question of whether removal of those alleged barriers is readily achievable. However, since Plaintiff failed to counter Defendant's motion for summary adjudication on all alleged ADA violations that are not addressed in the Advanced Design Consultants' Accessibility Improvements Plan, Defendant is granted summary adjudication on those issues. (Card Decl. P 4, Exh. B.) Therefore, the remaining alleged ADA violations that survive Defendant's motion for summary judgment include:

(1) Path of travel from the public way to the Theater's main entrance;

(2) Improvements to the disabled parking area, including installation of level parking and unloading area, proper striping, and signage; n8

> n8 As discussed above in footnote 7, however, Plaintiff does not have standing to argue that the lack of detectable warnings in the route between the accessible parking spaces and Theater constitutes a violation of the ADA.

(3) Ramps, stairs, and landings at the main entrance;

(4) Removal of barriers in the men's [*24] restroom; and

(5) Removal of barriers in the women's restroom.

Only those improvements illustrated in the Advanced Design Consultants' Accessibility Improvements Plan survive summary adjudication.

C. CBC

Defendant meets its initial burden of production under *Rule 56* for summary judgment on Plaintiff's state law claims for violations of the CBC because it points to an absence of evidence establishing a violation of the applicable CBC. (Blackseth Decl. PP 7-8.) For the reasons set forth in Part II above, those portions of Card's declaration analyzing the Theater under the 1984 CBC are stricken. Consequently, Plaintiff fails to show that a genuine issue of material fact exists on her claim under *section 19955 of the California Health and Safety Code. Cal. Health & Saf. Code § 19958.6*. Similarly, Plaintiff fails to create a genuine issue of material fact on her claim under the Unruh Civil Rights Act or the California Disabled Persons Act for violations of the applicable CBC. *Cal. Civ. Code § § 51(d), 54.1(a)(3)*. Therefore, Defendant is granted summary adjudication on Plaintiff's claim under *section 19955 of the California Health and Safety Code*. [*25] Defendant is also granted summary adjudication on Plaintiff's claims under the Unruh Civil Rights Act and the California Disabled Persons Act for violations of the CBC.

In addition, Defendant is grated summary adjudication on Plaintiff's claim for negligence per se because Plaintiff conceded that she does not seek actual damages. (Tr. of Mar. 8, 2005, Hr'g at 29:24-30:2.)

CONCLUSION

The parties' cross-motions for sanctions are denied. Defendant's objection to Card's analysis of the Theater under the 1984 CBC is sustained, and paragraphs 7 and 8 of Card's declaration, as well as those portions of paragraph 9 analyzing the Theater under the 1984 CBC, are stricken. Plaintiff's motion for summary judgment is denied. Defendant's motion for summary judgment on Plaintiff's claims under the ADA, the Unruh Civil Rights Act, and the California Disabled Persons Act is denied. Defendant is granted summary adjudication on Plaintiff's claim under *section 19955 of the California Health and Safety Code* and on Plaintiff's negligence per se claim. Defendant is granted summary adjudication on Plaintiff's claims under the Unruh Civil Rights Act and the California Disabled [*26] Persons Act as to alleged violations of the CBC. Defendant is also granted summary adjudication on Plaintiff's claims under the Unruh Civil Rights Act, the California Disabled Persons Act, and the ADA as to alleged violations of the ADA, except for those alleged ADAAG violations addressed in the Advanced Design Consultants' Improvements Plan.

IT IS SO ORDERED.

/s/ Garland E. Burrell, Jr.

DATED: August 3, 2005

United States District Judge